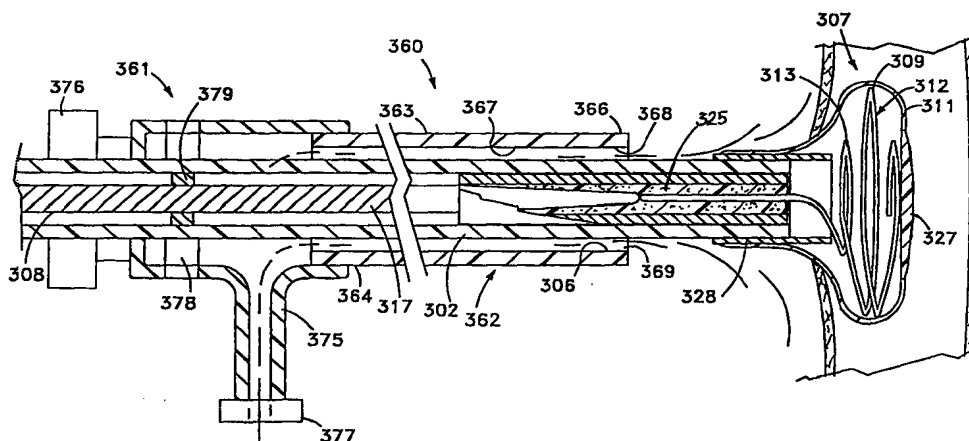




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(54) Title: EXPANSILE DEVICE FOR USE IN BLOOD VESSELS AND TRACTS IN THE BODY AND TENSION APPLICATION DEVICE FOR USE THEREWITH AND METHOD



## (57) Abstract

This invention is a device (360) for expansion within a blood vessel having a wall defining a lumen in the body. The device comprises a first elongate tubular member (302) having proximal and distal extremities, and having a longitudinal axis. An expansile member (309) is carried by the distal extremity of the first elongate tubular member, and is movable between contracted and expanded positions. The expansile member has a predetermined configuration in the expanded position. A deformable membrane (311) covers the expansile member, and is sized so as to be capable of overlying and underlying the expansile member in the expanded position. Deployment means (361) are carried by the proximal extremity of the first elongate tubular member, and are adapted to be operated by the human hand for controlling movement of the expansile member between the contracted and expanded positions.

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**EXPANSILE DEVICE FOR USE IN BLOOD VESSELS AND TRACTS IN THE  
BODY AND TENSION APPLICATION DEVICE FOR USE THEREWITH AND  
METHOD**

5           This is a continuation-in-part of prior application  
Serial No. 08/798,870, filed February 11, 1997.

          This invention relates to an expansile device and  
tension application device for use therewith, for use in  
vascular and non-vascular tracts in the human body and  
10   method and more particularly for percutaneous occlusion of  
vascular access sites in the human body.

          Percutaneous access to the blood vessels and organs of  
the human body for diagnosis and treatment of disease  
processes has heretofore been accomplished. Percutaneous  
15   vascular procedures are performed involving the coronary,  
peripheral and cerebral vasculature. These procedures  
include coronary and peripheral angiography, angioplasty,  
atherectomies, coronary retroperfusion and retroinfusion,  
cerebral angiograms, treatment of strokes, cerebral  
20   aneurysms and the like. Patients undergoing such procedures  
are often treated with anti-platelet drugs, anticoagulants  
such as heparin, thrombolytics, or a combination thereof,  
all of which interfere with coagulation making it more  
difficult for the body to seal a puncture site. Various

5 devices and methods have heretofore been utilized, however,  
they all have had deficiencies, including the use of  
complicated devices and methods. In addition, difficulties  
are still encountered in obtaining good seals. There is  
therefore a need for a device and method for percutaneous  
10 access and occlusion of vascular access sites and other  
puncture sites and natural tracts in the human body which  
overcome the deficiencies of prior art devices and methods.

In general, it is an object of the present invention to  
provide a closure device and method for percutaneous access  
15 and occlusion of vascular access sites, other puncture sites  
and natural tracts in the human body which will make  
possible a positive seal of the puncture site or tract  
promoting rapid healing of the puncture site or tract.

Another object of the invention is to provide a closure  
20 device and method of the above character which can be easily  
and reliably used.

Another object of the invention is to provide a closure  
device and method of the above character in conjunction with  
which a biological sealant is used by introduction into the  
25 puncture site or natural tract.

Another object of the invention is to provide a closure  
device and method of the above character which leaves a  
small enough opening after removal of the closure device so  
that the biological sealant will seal the remaining opening.

30 Another object of the invention is to provide a closure  
device and method of the above character which enables  
continued substantially unobstructed blood flow during  
deployment and use of the closure device.

Another object of the invention is to provide a closure  
35 device and method of the above character in which no foreign  
body remains in the blood vessel.

5           Another object of the invention is to provide a closure device and method of the above character that permits early ambulation of patients and avoids prolonged bed rest.

10           Another object of the invention is to provide a closure device and method of the above character which reduces the risk of bleeding, formation of arteriovenous fistula, formation of pseudoaneurysm, thrombosis with distal embolization and infection.

15           Another object of the invention is to provide a closure device and method of the above character that reduces the risk of causing ischemia of an extremity.

          Another object of the invention is to provide a closure device and method of the above character that is inexpensive, quick, safe, easy to use and is disposable.

20           Another object of the invention is to provide an expansile device and method of the above character in which the configuration of an expansile assembly is determined by countervailing mechanical forces of an expansile member and a membrane.

25           Another object of the invention is to provide an expansile device and method of the above character in which tensioning means is provided for reversibly maintaining engagement of the expansile assembly against the vessel wall of a puncture and to free the operator's hands from having to hold the device after it is correctly deployed in the  
30           puncture.

          Another object of the invention is to provide an expansile device and method of the above character in which tensioning means is provided for reversibly maintaining engagement of the expansile assembly against the vessel wall  
35           of a puncture by applying a substantially constant force of tension over a range of motion.

5 Additional objects and features of the invention will appear from the following description in which the preferred embodiments and the methods using the same are described in conjunction with the accompanying drawings.

10 Figure 1 is a side-elevational view partially in section of a closure device for obtaining percutaneous access and occlusion of puncture sites in the human body incorporating the present invention and having closure means in a de-deployed or retracted position.

15 Figure 2 is a cross-sectional view taken along the line 2-2 of Figure 1.

Figure 3 is a side-elevational isometric view of the distal end of the device shown in Figure 1 with the closure means in a deployed or extended position.

20 Figure 4 is a cross-sectional view taken along the line 4-4 of Figure 3 and shows the manner in which a seal is formed with respect to a puncture.

Figures 5A-5D are cartoons demonstrating the method of using the device of the present invention for occluding a vascular access or puncture site.

25 Figure 6 is a partial isometric view of an alternative closure assembly for the closure device shown in Figure 1.

Figure 7 is a side-elevational view partially in section of another embodiment of the closure device incorporating the present invention.

30 Figure 8 is a cross-sectional view taken along the line 8-8 of Figure 7.

Figure 9 is a cross-sectional view taken along the line 9-9 of Figure 8.

35 Figure 10 is a side-elevational isometric view of the distal end of the device of Figure 8 with the closure assembly in a deployed or expanded position.

5           Figure 11 is a side-elevational view partially in section of another embodiment of the closure device incorporating the present invention.

          Figure 12 is a cross-sectional view taken along the line 12-12 of Figure 11.

10          Figure 13 is a partial side-elevational view of the distal extremity of the closure device of Figure 11 with the closure mechanism in a deployed position.

          Figure 14 is a view looking along the line 14-14 of Figure 13.

15          Figure 15A is a side-elevational view partially in section of the proximal end of another embodiment of the closure device incorporating the present invention.

          Figure 15B is a side-elevational view partially in section of the distal end of the embodiment shown in Figure 15A.

20          Figure 16 is a side-elevational view partially in section of the distal end of the device of Figure 15 with the closure assembly in a deployed position.

          Figure 17 is a view partially in section taken along the line 17-17 of Figure 16.

25          Figure 18 is a side-elevational view partially in section of another embodiment of the closure or expansile device incorporating the present invention.

          Figure 19 is a side-elevational view partially in section of the distal end of the device of Figure 18 with the expansile assembly in an free or expanded position without the covering membrane.

30          Figure 20 is an plan view of the top of the tensioning device of the present invention taken along the line 20-20 of Figure 23.

35          Figure 21 is a cross-sectional view taken along the

5 line 21-21 of Figure 23.

Figure 22 is a side-elevational view partially in section of the tensioning device of the present invention in the open position.

10 Figure 23 is side-elevational view partially in section of the tensioning device of the present invention in the closed, neutral position.

Figure 24 is a cross-sectional view of the device of Figure 18 with one embodiment of the biological sealant introducing means.

15 Figure 25 is an side-elevational view partially in section of another embodiment of the expansile device of the present invention shown with its biological sealant introducing means.

20 Figure 26 is a cross-sectional view taken along the line 26-26 of Figure 25.

Figure 27 is an isometric view of the device in Figure 18 with another embodiment of the biological sealant introducing means.

25 Figure 28 is an isometric view the third elongate member that obturates the second lumen in the biological sealant introducing means of Figure 27.

Figure 29 is a cross section view taken along the line 29-29 of Figure 27.

30 Figure 30 is a cross-sectional view of another embodiment of the third elongate tubular member which is part of the biological sealant introducing means of Figure 27.

35 Figure 31 is an isometric view of the device in Figure 18 with another embodiment of the biological sealant introducing means.

Figure 32 is a cross-section view taken along the line



5 32-32 of Figure 30.

10 In general, the closure device of the present invention is used for the percutaneous occlusion of a puncture site and natural tract in the human body. The human body has an outer layer of skin and inner layers of tissue surrounding a blood vessel having a lumen therein defined by a vessel wall. A puncture site traverses these layers and, in the case of a vascular access puncture, the vessel wall. The closure device comprises a flexible elongate tubular member having proximal and distal extremities, an outer diameter and extending along a longitudinal axis. The flexible elongate tubular member has a first lumen extending therethrough from the proximal extremity to the distal extremity. A closure assembly is carried by the distal extremity and includes a closure mechanism and an impermeable membrane at least partially covering the closure mechanism. Deployment means carried by the proximal extremity of the flexible elongate tubular member are adapted to be operated by the human hand. The deployment means extends through the flexible elongate tubular member, includes a push-pull wire and is coupled to the closure assembly for moving the closure assembly from a de-deployed or contracted position for introduction into and through a puncture to a deployed position for forming a seal occluding the puncture.

30 More specifically, as shown in Figures 1-4, the closure device 21 of the present invention for percutaneous occlusion of puncture sites and natural tracts consists of a flexible elongate tubular member 22 formed of a suitable plastic material such as polyethylene or polyurethane or polyimide. The flexible elongate tubular member 22 has a longitudinal axis and proximal and distal extremities 23 and

5 24. The flexible elongate tubular member 22 is provided  
with a main circular in cross-section first lumen 26 which  
may be centrally disposed extending from the proximal  
extremity 23 to the distal extremity 24. It is also  
provided with an additional or second lumen 27 which may be  
10 crescent-shaped as shown in cross-section in Figure 2  
extending from the proximal extremity 23 to the distal  
extremity 24 where it opens through an external port 28. A  
plug 29 of a suitable material such as plastic is placed in  
the lumen 27 to occlude the lumen 27 distal of the port 28.

15 The flexible elongate tubular member 22 is of a  
suitable size, as for example a diameter ranging from 1-9  
French corresponding to an outside diameter ranging from  
approximately .3 to 3.0 millimeters. The flexible elongate  
tubular member has a suitable length as for example 15-30  
20 centimeters with the external port 28 being disposed a  
suitable distance adjacent to and proximal of the closure  
assembly 32, as for example from 1-10 millimeters up to  
several centimeters. The first lumen 26 may have an inside  
diameter ranging from .015" to 0.080", preferably .020"-  
25 .030" while the second lumen 27, if crescent-shaped may have  
a long axis dimension of approximately 0.015" to 0.080".

Closure means in the form of a closure assembly 32 is  
carried by the distal extremity 24 of the flexible elongate  
tubular member 22 and is coupled or secured to deployment  
30 means or mechanism 33 for movement from a contracted,  
retracted or de-deployed position to an expanded or deployed  
position. The closure assembly 32 includes a closure  
mechanism 34 and an impervious membrane 36 which covers the  
closure mechanism 34. The closure mechanism 34 as shown in  
35 Figures 3 and 4 is in the form of a complex geometrical  
configuration, as for example a coil, when in a free state.

5 The coil 34 is formed of a suitable material which can be elongated without permanent deformation but when freed or unconstrained has a substantial portion thereof which will return to a generally planar or disk-like configuration to which it has been annealed. One material found to be  
10 particularly suitable for such an application is a super-elastic or shape memory element as formed of a nickel/titanium alloy, often called Nitinol. The coil 34 has a plurality of generally circular turns 37 and has first and second ends 38 and 39 secured to the deployment  
15 mechanism 33 in a manner hereinafter described. The turns 37 of the coil 34 lie in a single plane which is generally perpendicular to the longitudinal axis of the flexible elongate tubular member 22.

The coil 34 has a diameter which is selected to overlap  
20 a puncture site as hereinafter described to occlude the puncture site. Typically, a suitable diameter such as 3 to 7 millimeters and preferably approximately 5 millimeters is used. In the de-deployed configuration the constrained coil 34 has a suitable diameter ranging from .1 mm to 3.0 mm.  
25 The coil 34 can be formed of wire having a diameter ranging from 0.002" to 0.004" (.05 to .1 millimeters) and preferably about 0.003" (.076 millimeters). Alternatively, it can be formed of ribbon generally rectangular in cross-section and can have a thickness of approximately 0.001" to 0.002" (.025  
30 to .05 mm.) and a width of approximately 0.003" to 0.005" (.076 to .13 millimeters).

The deployment means or mechanism 33 consists of a push-pull wire 41 which is slidably disposed in and extending through the first or main lumen 26 and has  
35 proximal and distal extremities 42 and 43. The push-pull wire 41 is formed of a suitable material such as stainless

5 steel and has a suitable diameter as for example 0.005" to  
0.032". Means is provided for securing the two ends 38 and  
39 of the coil 34 to the distal extremity 43 of the push-  
pull wire 41 and consists of solder forming joints or  
adhesively bonded joints. As shown in Figure 1 the proximal  
10 end 42 of the push-pull wire 41 extends out of the proximal  
extremity 23 of the flexible elongate tubular member 22 and  
is operatively connected to a handle assembly 44 as  
hereinafter described.

The handle assembly 44 is formed of a body 46 of  
15 suitable material such as plastic and is mounted on the  
proximal extremity 23 of the flexible elongate tubular  
member 22. The handle 44 is sized so it is adapted to be  
grasped by the human hand and is provided with means for  
operation of the push-pull wire 41 which includes a button  
20 47 adapted to be engaged by a finger of the hand holding the  
handle. The button 47 is mounted on a protrusion 48 which  
is slidably mounted in a longitudinally extending slot 49 in  
the handle 44 and is movable between first and second  
positions for deploying the coil 34 from a retracted or  
25 contracted elongate position constrained within the flexible  
elongate tubular member 22 to an expanded position outside  
of the tubular member 22. The proximal extremity 42 of the  
push-pull wire 41 is secured to the protrusion 48 in a  
suitable manner such as a wire clamp or adhesive (not  
30 shown). The slot 49 opens into sideways extending notches  
51 and 52 provided in the body which can receive the  
protrusion 48 in either the first or second position to  
retain the push-pull wire 41 in the desired position as  
hereinafter described.

35 The closure means 32 also includes a flexible  
impermeable membrane 36 which is carried by and secured to

5 the distal extremity 24 of the flexible elongate tubular member 22. It is desired that this membrane 36 be very flexible and it therefore has a wall thickness ranging from 0.0005" to 0.010" (.0127 to .076 millimeters) and preferably 0.001" (.025 millimeters). It can be formed of any suitable  
10 flexible impermeable material such as elastomeric and non-elastomeric materials. For example, latex or silicone have been found to be suitable. The membrane 36 should be substantially impermeable to blood and other liquids. It is preferably formed as a tubular sock which can have an  
15 elongate generally cylindrical configuration with one closed end 54 and the other end circumscribed by an opening 56 which is defined by a rim 57 of the impermeable membrane. This rim 57 is circumferentially secured to the distal extremity 24 in a suitable manner such as by an adhesive  
20 (not shown) and preferably interiorly within the first or main lumen 26. However, if desired, the rim 57 can also be affixed exteriorly to the outer surface of the tip 31 of the distal extremity 24 of the flexible elongate tubular member 22. The impermeable membrane 36 is formed in such a manner  
25 so that it can, upon manufacture of the device 21, be disposed internally of the distal extremity 24 of the flexible elongate tubular member 22 and be folded inwardly with folds 58 in the main lumen 26 to accommodate closure mechanism 34 in a constrained, retracted or contracted or  
30 de-deployed position as shown in Figure 1. It also has the flexibility of being moved outwardly by operation of the push-pull wire 41 to the sock-like dotted line position 61 shown in Figure 1.

35 The impermeable membrane 36 also can be caused to assume a disk-like planar configuration as shown by the dotted-line position 62 in Figure 1. This is accomplished

5 by operation of the deployment mechanism 33 to move the  
push-pull wire 41 distally to urge the closure mechanism 34  
distally to move out of the lumen 26 into the dotted-line  
position 61. As soon as the closure mechanism 34 is clear  
of the main lumen 26, it will expand into its memorized  
10 configuration. As this expansion is occurring, the membrane  
36 covering the coil 34 is caused to move from the sock-like  
configuration 61 to the disk-like circular configuration 62  
so that the membrane 36 is disposed on opposite sides of the  
closure mechanism 34 and lies in generally parallel planes  
15 which are generally perpendicular to the longitudinal axis  
of the flexible elongate tubular member 22 for  
percutaneously occluding a puncture as hereinafter  
described. The deployed closure mechanism 34 is  
sufficiently rigid so as to provide a supporting framework  
20 for the membrane 36.

The closure device 21 also consists of biological  
sealant introducer means 81 carried by the handle 44 and the  
flexible elongate tubular member 22 for introducing a  
biological sealant into a puncture proximal of the closure  
25 assembly 32 after the closure assembly 32 has been  
positioned. The biological sealant is of a suitable type  
such as a two-component fibrin glue, thrombin, fibrin,  
collagen-thrombin, collagen, Avitene (trademark), Gelfoam  
(trademark), cellulose, gelatin, and mixtures or slurries  
30 thereof. It should be appreciated that other biological  
sealants or pharmacological agents may also be introduced  
into a puncture utilizing this device.

The biological sealant introducer means 81 can consist  
of a fitting of a suitable type such as a wye adapter 82  
35 which is provided with first and second arms 83 and 84 with  
first and second syringes 86 and 87 removably mounted

5 thereon on and containing the two separate constituents of  
fibrin glue being used as the biological sealant. The  
fitting 82 is connected to a flexible tubular member 91  
which is sealed into the handle 44 and is provided with a  
lumen 92 therein in communication with the lumen (not shown)  
10 of the arms 83 and 84. The distal end of the flow passage  
92 in the tubular member 91 is aligned to be in  
communication with the second lumen 27 of the flexible  
elongate tubular member 22 so that when the syringes 86 and  
87 are operated the biological sealant components are mixed  
15 and pass through the flow passage 92 existing via the  
external port 28 of the second lumen 27.

Operation and use of the device 21 in performing the  
method of the present invention in the percutaneous access  
and occlusion of vascular access sites and other puncture  
20 sites in the human body may now be described in conjunction  
with the cartoons shown in Figures 5A-5D. Let it be assumed  
that a percutaneous femoral arterial catheterization is to  
be performed. After sterile preparation, a thin-walled  
hollow needle with syringe (not shown) is percutaneously  
25 inserted through the skin 101, the underlying subcutaneous  
tissue 102 and then through the wall 103 defining the lumen  
104 of a vessel 107 such as the femoral artery to form a  
puncture 106. Intra-arterial access is confirmed by the  
aspiration of arterial blood. A flexible wire (not shown)  
30 is then passed through the needle into the artery 107 and  
the needle is removed, leaving only the wire in place in the  
puncture 106. A vessel dilator (not shown) with a shorter  
conventional over-lying sheath 111 is passed over the wire  
through the puncture 106 into the lumen 104 after which the  
35 wire and dilator are removed. The sheath 111 extends from  
outside the patient through skin 101 and subcutaneous

5 tissues 102 and through the wall 103 into the lumen 104 as  
shown in Figure 5A. Various diagnostic and therapeutic  
catheters and other similar medical devices can be passed  
through the sheath 111, whose diameter can range from 3 to  
24 French, to perform desired procedures, as for example an  
10 angioplasty procedure during which time anti-coagulants such  
as heparin have been introduced. At the conclusion of any  
such procedure, such instruments are removed leaving only  
the sheath 111 in place.

Let it be assumed that it is now desired to seal the  
15 puncture 106. The closure device 21 of the present  
invention with the closure assembly 32 in the retracted  
position as shown in Figure 1 is inserted into the sheath  
111 while maintaining standard sterile precautions. The  
distal extremity 24 of the flexible elongate tubular member  
20 22 is passed through the sheath 111 and into the lumen 104  
so that it extends a short distance up to several inches  
beyond the distal extremity of the sheath 111 as shown in  
Figure 5A. The sheath 111 is then slowly, incrementally  
withdrawn proximally while maintaining the device 21 as  
25 stationary as possible. As can be seen from Figure 5B, the  
flexible elongate tubular member 22 has a length so that the  
sheath can be removed from the puncture 106 while retaining  
the distal extremity 24 in the lumen 104 and without  
removing the handle 44. When the sheath 111 has been  
30 withdrawn as shown in Figure 5B, the closure assembly 32 may  
be deployed by operation of the deployment mechanism 33.  
Alternatively, the distal extremity 24 of the flexible  
elongate tubular member 22 can be passed into the lumen 104  
a slightly greater distance, the device 21 deployed with the  
35 sheath 111 still in position, and then both the sheath 111  
and device 21 slowly withdrawn so that the sheath 111 is



5 removed from the lumen 104 with the deployed device 21  
appropriately positioned in the lumen 104.

Before deployment of the closure assembly 32, the  
finger button 47 is in its most proximal-most position with  
the protrusion 48 being seated in the notch 51 as shown in  
10 Figure 5A. Now let it be assumed that it is desired to move  
the closure assembly 32 from a contracted or retracted  
position where it is disposed within the first main lumen  
26. When it is desired to move the closure assembly 32 to  
an expanded or open position, the button 47 is retracted  
15 from the notch 51 and slidably advanced along the slot 49 to  
push the distal extremity 43 of the push-pull wire 41  
distally to cause the Nitinol closure mechanism 34 to be  
advanced distally and to carry the folded impermeable  
membrane 36 out of the first or main lumen 26 to cause it to  
20 assume a sock-like shape as shown in position 61 in Figure  
1. Continued forward movement of the finger button 47  
causes further longitudinal movement of the push-pull wire  
41 which causes further distal movement of the closure  
mechanism 33 until it clears the first lumen 26 so that it  
25 is substantially free to cause it to expand into its super-  
elastic or shape memory form of a coil to carry with it the  
flexible impervious membrane 36 to assume the disk-like  
configuration represented by position 62 as shown in Figures  
1 and 4. The finger knob is then positioned so that the  
30 protrusion 48 is seated in the notch 52.

After the closure mechanism has been fully deployed,  
the handle 44 can be utilized to gradually retract the  
flexible elongate member 22 to ensure that the proximal  
surface of the flattened flexible membrane 36 is brought  
35 into close engagement with the inner surface of the wall 103  
forming the lumen 104 in which the closure assembly 32 is

5 disposed. This forms a liquid tight seal between the  
closure assembly 32 and the wall 103 immediately adjacent  
the puncture 106 which in turn enables accurate and  
effective deposition of the biological sealant into the  
10 puncture 106 as hereinafter described. Such a liquid tight  
seal is also necessary in connection with the present  
invention to prevent the leakage of blood through the  
puncture 106. This serves to prevent blood from interfering  
with attempts to safely and permanently occlude and seal the  
puncture 106 and to prevent inadvertent intravascular  
15 deposition of sealant.

The formation of a good seal between the occlusion  
assembly 32 and the wall 103 of the vessel 107 can be  
ascertained in several ways. By way of example the absence  
of arterial blood in the puncture 106 serves to verify that  
20 a good seal has been made. Attempts to aspirate blood from  
the second lumen 27 with no blood return therefrom also  
indicates accurate placement of the device 21.  
Alternatively, fluoroscopy can be utilized to check the  
position of the closure assembly 32. This is made possible  
25 because of the radio opacity of the closure mechanism 34.  
Radio opaque dyes may also be utilized to ascertain whether  
the puncture has been effectively sealed. A small amount of  
radio opaque dye may be injected into the subcutaneous  
tissue adjacent the puncture 106. If fluoroscopy  
30 demonstrates intravascular dye then there is inadequate  
placement of the closure assembly 32. If perchance there is  
any leakage, the button 47 can be engaged by the finger and  
retracted out of the notch 52 and proximally for a slight  
distance and then moved distally to re-deploy the mechanical  
35 assembly 32, thereafter grasping the handle 44 and pulling  
the flexible elongate member 22 proximally to again

5 reestablish a seal with the wall 103 adjacent the puncture 106.

As soon as it has been established that a good seal has been formed in the manner hereinbefore described between the closure assembly 32 and the wall 103 adjacent the puncture 106, a biological sealant to be utilized can be introduced into the puncture 106 to provide a sealant 116 which extends throughout the puncture 106 from immediately outside the vessel 107 up to as far as the outer surface of the skin 101 as shown in Figure 5C. It should be appreciated, however, that it may not be necessary to introduce an amount of sealant so great as to cause it to extend proximally to the skin. Assuming that the biological sealant is a fibrin glue supplied in two ports in the syringes 86 and 87, the physician utilizing the closure device 21 while holding the handle 44 in one hand utilizes the other hand to operate the syringes 86 and 87 to cause the constituents of the biological sealant to be introduced into the wye adapter 82 where they are mixed with each other and introduced through the tubular member 91 and into the second lumen 27, thence through the exit port 28 which is adjacent the closure assembly 32. It should be appreciated that in addition to holding the handle 44 in order to maintain engagement of the closure assembly 32 with the vessel wall 103, any suitable device by way of example a pin-vise may be applied to the flexible elongate tubular member 22 immediately adjacent the skin 101 so that the engagement is maintained and the physician has a free hand. The fibrin glue seals the innermost tissue layers in the puncture 106 and then, as hereinbefore described, can backfill the puncture 106 through the subcutaneous tissue 102 and to the skin 101, surrounding the distal extremity 24 of the flexible elongate

5 tubular member 21 as shown in Figure 5C. If necessary, the  
completion of this backfilling can be observed by the fibrin  
glue exiting from the puncture 106. As soon as this occurs,  
the physician terminates further movement of the syringes 86  
and 87 and then while still holding the handle 44 to retain  
10 the closure assembly 32 in place, permits the fibrin glue to  
set up or cure within the puncture 106 for a period of time  
suitable to permit the fibrin glue to form a sticky adherent  
clot in the puncture 106 but to prevent the fibrin glue  
forming a clot which is too firm so as to preclude easy  
15 withdrawal of the closure device 21. Typically this ranges  
from a period of time of 30 seconds to 15 minutes and  
preferably a period of time of approximately 1-2 minutes.  
The aforementioned biological sealants only adhere to  
collagen-containing tissues which prevents them from bonding  
20 to the flexible elongate tubular member 22. As soon as the  
physician determines that the fibrin glue has assumed the  
desired state, the button 47 carried by the handle 44 is  
engaged by the finger of the physician's hand and moved out  
of the slot 52 and then retracted proximally in the slot 49  
25 to cause proximal movement of the push-pull wire 41 to cause  
a gradual straightening of the closure mechanism 34 to bring  
it substantially within the interior of the lumen 26 thereby  
permitting collapse of the flexible membrane 36 so that it  
can assume a generally sock-like configuration. Thus as  
30 soon as the button 47 has been moved to its most proximal  
position and moved into the notch 51, the closure device 21  
can gently be pulled from the seal 116 provided in the  
puncture 107. The hole (not shown) left in the sealant 116  
after withdrawal of the flexible elongate tubular member 22  
35 and the membrane 36 carried thereby closes on itself due to  
the sufficiently gel-like state of the fibrin glue or other

5 agent. Thereafter, the site of the puncture 106 is observed  
to ascertain whether or not bleeding is occurring therefrom.  
An excellent biological seal is formed with nothing  
remaining at the puncture site except for the biological  
sealant which within a relatively short period of time as  
10 for example 1-2 weeks will be absorbed by the body.

From the foregoing it can be seen that there has been  
provided a closure device and a method for utilizing the  
same which makes it possible to quickly and efficaciously  
close the puncture which has been made necessary for  
15 performing a desired medical procedure as for example an  
angioplasty procedure. An excellent seal is formed even  
though anticoagulants have been introduced into the blood of  
the patient during the procedure to prevent the formation of  
clot. The application of fibrin glue in this manner permits  
20 the formation of a good clot to seal the puncture without  
danger of re-bleeding occurring.

It also should be appreciated that during this  
procedure in performing the closure of the puncture site,  
blood can continue to flow substantially unimpeded through  
25 the lumen 104 of the vessel. This lack of obstruction is  
made possible because of the small size of the distal  
extremity of the closure device 21 and also because of the  
small size of the closure assembly 32 carried by the distal  
extremity 24 of the device 21. When the closure assembly 32  
30 is deployed as hereinbefore described, it has a relatively  
small diameter in comparison to the size of the lumen into  
which it is introduced. In addition it has a flat planar  
configuration which, when brought into engagement with the  
inner surface of the wall 103, is substantially flush with  
35 the inner surface of the wall 103. Even when the closure  
assembly 32 is being de-deployed it occupies very little

5 space as it is being withdrawn.

Another embodiment of the closure assembly is shown in Figure 6 which can be utilized in place of the closure assembly 32 on the distal extremity 24 of the flexible elongate tubular member 22 carried by the handle 44. As shown, the closure assembly 131 consists of a closure mechanism 132 which is covered by a flexible impermeable membrane 133. The closure mechanism 132 can be formed of the same super-elastic or shape memory material as the closure mechanism 34 but rather than having a coil-like configuration such as shown in Figure 1, 3 and 4, it includes a different complex geometrical configuration as for example a flower-like configuration as shown in Figure 6. Thus it can be formed of a Nitinol ribbon or wire of a single length having ends 137 and 138 which are secured to the distal extremity 43 of the push-pull wire 41 in a manner similar to that hereinbefore described. The wire ribbon 136 has been annealed to have a super-elastic or shape memory form for the flower-like configuration shown in which a plurality of loops 141, as for example three as shown are provided on the wire ribbon 136. The loops 141 are oval shaped, approximately equal in size and have curved outer extremities 142. The loops 141 lie in a single plane and have the longitudinal axes of the loops spaced apart by equal angles of about  $120^\circ$ . It should be appreciated that if desired, additional loops can be provided with the loops being spaced equally over  $360^\circ$ . Since the loops 141 correspond to the shape of petals of a flower, the configuration shown in Figure 6 can be described as a flower-like arrangement in which the loops 141 lie in a common plane which is generally perpendicular to the longitudinal axis of the flexible elongate member 22.

5           The membrane 133 which forms a part of the closure  
assembly 131 can be formed of the same material as the  
membrane 36 and can be secured in the same manner to the  
tubular member 22 so that when the closure mechanism 132 is  
in a retracted position within the lumen 26 it also can be  
10 provided with folds in the same manner as the membrane 36.  
The closure mechanism 132 can be straightened in a similar  
manner and brought into a retracted position similar to the  
closure mechanism 34. The closure assembly 131 also can be  
deployed in a similar manner. When deployed, it will cause  
15 the impermeable membrane to assume a generally flat planar  
configuration which is still substantially in the form of a  
circle as determined by the outer curved extremities 142 of  
the loops 141 with very slight variations from a circle  
between the outer extremities of adjacent loops. Thus a  
20 good seal can be formed with the wall 103 of the vessel 107  
in the same manner as with the closure assembly 32. Thus it  
can be seen that the operation and use of the closure  
assembly of Figure 6 can be very similar to that described  
for use of the closure assembly 32 and with generally the  
25 same attendant advantages. It should be appreciated that  
other arrangements of closure mechanisms can be provided for  
causing appropriate deployment of the impervious membrane to  
form a seal without departing from the scope of the present  
invention. The sizes and shapes of the closure assemblies  
30 can be selected to be appropriate for the puncture to be  
occluded. Thus for example the flower arrangement shown in  
Figure 6 can have the same size as the coil arrangement  
shown in Figures 1, 3 and 4 or alternatively can be  
decreased or increased in size as desired. Furthermore, by  
35 altering the number of petals or loops, the shape can also  
be varied from that of a circle to that of substantially a

5 triangle or square.

Another embodiment of a closure device incorporating the present invention is shown in Figure 7-10. The closure device 151 is shown therein. The closure device is very similar to that shown in Figure 1 with the principal  
10 difference being in the type of closure assembly utilized on the distal extremity 24 of the flexible elongate tubular member 22. Thus all of the parts of the closure device 151 carry the same numbers as the closure device 21 shown in Figure 1 to the distal extremity 24 on which the closure  
15 assembly 156 is carried. The closure assembly 156 consists of a closure mechanism 157 which is covered by a flexible impermeable membrane 158. The closure mechanism 157 consists of a plurality of rod-like elements 161, struts or arms of at least three in number which are circumferentially  
20 spaced apart and have proximal ends 162 which are embedded in the distal extremity 24 of the flexible elongate tubular member 22. This can be accomplished in a suitable manner such as by extruding the plastic forming the tubular member over the proximal ends 162 or alternatively by placing  
25 axially aligned bores in the distal extremity 24 and securing the proximal ends 162 therein by suitable means such as an adhesive. The exposed portions of the rod-like elements 161 as shown in Figure 7 are formed of a suitable material such as stainless steel or Nitinol and are inclined  
30 inwardly in a distal direction to provide a truncated cone-like shape. The distal ends 163 of the rod-like elements 161 can be bonded or fastened together in a suitable manner such as by welding or solder to provide a generally hemispherical tip 166 which is also secured to the distal  
35 extremity 43 of the push-pull wire 41. The rod-like elements 161 are provided with weakened regions or notches



5 or memorized bending points 171 approximately a  
substantially equal distance from the proximal and distal  
ends 162 and 163 to form hinge points 171. The lengths of  
the exposed portions of the rod-like elements 161 may be  
selected to correspond to a selected diameter of the closure  
10 mechanism 157.

The membrane 158 which covers the closure mechanism 157  
has a sock-like configuration with a closed end 176 which  
overlies the hemispherical tip 166 and an open end which  
is defined by the circular rim 177 which is bonded to the  
15 exterior surface of the distal extremity 24 of the flexible  
elongate tubular member 22 by an adhesive (not shown).

Operation and use of the closure device 151 may now be  
briefly described as follows. It should be appreciated that  
imposition of the button 47 with respect to the notches 51  
20 and 52 is reversed in that the button is positioned in the  
notch 52 when the closure assembly 156 is in the de-deployed  
or unexpanded condition as shown in Figure 7 rather than in  
the notch 51. A closure device 151 can be introduced into  
the sheath 111 in the unexpanded condition shown in Figure 7  
25 in the manner hereinbefore described with respect to the  
device 21 and after the closure assembly 156 is within the  
lumen 104 of the vessel 107 the closure assembly 156 can be  
deployed or moved to an expanded position by moving the  
button 47 proximally to cause a pulling force to be applied  
30 to the hemispherical tip 166 to cause a pushing force to be  
applied to the rod-like elements 161 to cause them to be  
bowed outwardly and to bend or fold about the hinge points  
171 and at the same time to carry with them the membrane  
158. Continued movement of the button 47 proximally until  
35 it reaches the slot 51 will cause the rod-like elements 161  
to cause the portions 161a to generally overlie the portions

5 161b and to extend radially from the longitudinal axis of  
the flexible elongate tubular member 22 at substantially  
right angles thereto as shown in Figure 10. The membrane  
158 covering the same is similarly caused to assume a  
generally circular disk-like configuration lying in a single  
10 plane which can be brought against the inner surface of the  
wall 103 of the vessel 107 in the same manner that the  
closure assembly 32 hereinbefore described is brought into  
contact with the wall. Thereafter the procedure  
hereinbefore described can be used for forming the seal with  
15 the puncture 106 and to permit introduction of the  
biological sealant. After this procedure has been  
completed, the closure mechanism 157 can be de-deployed by  
moving the same to an unexpanded condition by moving the  
knob 47 proximally to cause the push-pull wire 41 to move  
20 the hemispherical tip 166 distally and to carry with it the  
membrane 158 until the closure assembly 156 assumes its  
original unexpanded or de-deployed generally cylindrical  
configuration which is in alignment with the longitudinal  
axis of the flexible elongate tubular member 22 as shown in  
25 Figure 7 after which the closure device 151 can be removed  
to form the desired occlusion for the puncture 106. It  
should be appreciated that by varying the number of rod-like  
elements the shape of this closure assembly can similarly be  
varied so that it may be deployed into planar triangular,  
30 square or oval configurations as well. This closure  
assembly 156 also differs from the closure assembly 32 and  
the closure assembly 131 in that it can be formed without  
the use of super-elastic or shape memory material.

Another embodiment of a closure device incorporating  
35 the present invention is shown in Figures 11, 12 and 13 in  
which a closure device 191 is shown which is very similar to

5 the closure device shown in Figure 7 with the exception that  
the closure assembly carried by the distal extremity 24 of  
the flexible elongate tubular member 22 is of a different  
construction from the closure assembly 156. The closure  
assembly 196 differs from the closure assembly 156 in that  
10 the distal extremity 24 of the flexible elongate tubular  
member 22 carries an additional segment 192 of flexible  
elongate tubular material which has been bonded or annealed  
to the tip 31 of the distal extremity 24 of the flexible  
elongate tubular member 22 and which forms a part of a  
15 closure mechanism 197 which is covered by an impermeable  
flexible membrane 198. The additional segment 192 is  
constructed of a segment of flexible elongate tubular member  
which is extruded with only a main circular in cross-section  
first lumen and without an additional lumen. The second  
20 lumen 27 in this device 191 is blocked by the bonded or  
annealed additional segment 192 and thus no plug is  
required. To form the closure mechanism 197, the additional  
segment 192 of the flexible elongate tubular member 22 is  
provided with a plurality of circumferentially spaced apart  
25 longitudinally extending slits 201 of a suitable number to  
provide a plurality of arcuate segments as for example the  
four segments 24a, 24b, 24c and 24d as shown in Figures 11  
and 12. As hereinafter described since the segments 24a, b,  
c and d are formed of a flexible material, they can be bowed  
30 outwardly. The closure assembly 196 also includes a  
plurality of rod-like elements 202 similar to the rod-like  
elements 161 and formed of a suitable material such as  
stainless steel or Nitinol but because of the use of the  
arcuate segments 24a, b, c and d the rod-like elements 202  
35 need only be approximately one-half the length of the rod-  
like elements 161. The rod-like elements 202 like the rod-

5     like elements 161 can have a suitable diameter as for  
example 0.002" to 0.015" or preferably 0.002" to 0.003".  
The rod-like elements 202 are provided with proximal and  
distal ends 203 and 204. The proximal ends are embedded in  
the arcuate segments 24a, b, c and d in a suitable manner.  
10    For example, the plastic forming the segments can be  
extruded over the ends 203 or, alternatively, the segments  
can be provided with bores for receiving the ends 203 which  
are secured therein by suitable means such as an adhesive  
(not shown). The rod-like elements 202 extend distally and  
15    inwardly to form a truncated cone and have their distal ends  
204 interconnected by a generally hemispherical tip 206  
formed of solder or a weld which is also bonded to the  
distal extremity 43 of the push-pull wire 41 as shown in  
Figure 11. The rod-like elements 202 are provided with  
20    notches or weakened regions or memorized bending points to  
form hinge points 208 which are preferably in close  
proximity to the arcuate segments 24a, b, c and d so that  
the hinge points are close to the junctures between the ends  
203 and the adjoining segments 24a, b, c and d. The length  
25    of each of the arcuate segments 24a, b, c and d and each of  
the rod-like elements 202 is approximately equal and  
corresponds to the desired size of the closure mechanism  
197.

      The membrane 198 covers the closure mechanism 197 and  
30    has a conformation similar to that of the membrane 158 and  
is provided with a closed end 211 which overlies the  
hemispherical tip 206 and an open end circumscribed by a rim  
212 which is adhered to the additional portion 192 of  
flexible elongate tubular material annealed to the tip 31 of  
35    the distal extremity 24 of the flexible elongate tubular  
member 22 just proximal of the slits 201 which form the

5 segments 24a, 24b, 24c and 24d and is secured thereto by a suitable means such as an adhesive (not shown).

Operation and use of the closure device 191 as shown in Figures 11 and 12 is very similar to that described for the embodiment of the closure device 151 shown in Figure 7. The  
10 closure device as shown in Figure 11 has the closure assembly 196 in a de-deployed or un-expanded condition with the button 47 being disposed in the notch 52. In connection with sealing a puncture after the distal extremity 24 of the device 191, and in particular the closure mechanism 197, is  
15 disposed within the vessel 107 distal of the puncture 106, the closure assembly 196 can be deployed by moving the button 47 proximally to cause pulling on the pull wire 41 to apply compressive forces to the strut-like rod-like elements 202 to cause outward bowing of the same as well as the  
20 segments 24a, 24b, 24c and 24d with sharp bends occurring at the hinge points 208 just distal of the arcuate segments 24a, b, c and d. This outward bowing is continued so that the arcuate segments 24a, b, c and d are bent outwardly with respect to the longitudinal axis of the flexible elongate  
25 tubular member 22 and similarly the rod-like strut elements 202 are bowed outwardly with respect to the hemispherical tip 206 while carrying along with them the flexible impermeable membrane 198 until the rod-like elements 202 substantially overlies and are generally parallel with the  
30 segments 24a, b, c and d as shown in Figures 13 and 14 to form a planar disk-like conformation corresponding generally to the disk-like conformations of the embodiments of the closure devices hereinbefore described. Although the conformation as viewed in Figure 14 has a generally square  
35 configuration it can be readily appreciated that by providing additional segments in the distal extremity 24 and

5 a corresponding number of additional rod-like elements,  
additional arms can be provided for controlling the movement  
of the membrane 198 so that the outer margin of the membrane  
has a more generally circular configuration if that be  
desired. As heretofore described with other embodiments,  
10 the configuration may also be oval, triangular or square  
depending on the number of elements.

After the closure assembly 196 has been deployed as  
shown in Figures 13 and 14 it can be utilized in the manner  
hereinbefore described with the previous closure devices for  
15 forming a seal with the inner surface of the wall 103 and  
thereafter introducing a biological sealant. After this has  
been accomplished, the closure assembly 196 can be  
contracted and de-deployed by moving the button 47 from the  
notch 51 and pushing it distally to push the hemispherical  
20 tip 206 distally and to cause inward collapsing of the  
segments 24a, b, c and d and the rod-like strut elements 202  
until they have been moved into the original de-deployed or  
contracted positions as shown in Figure 11 and with the  
button 47 in the notch 52. Thereafter, the closure device  
25 191 can be retracted in a manner similar to that  
hereinbefore described with respect to the previous  
embodiments.

Another embodiment of a closure device incorporating  
the present invention is shown in Figures 15 and 16. The  
30 closure device 221 shown therein is similar to that shown in  
Figure 1 with the principal differences being that the  
device 221 utilizes a closure assembly on the distal  
extremity 24 of the flexible elongate tubular member 22 and  
a deployment means that incorporate elements that are  
35 similar to both the device shown in Figure 1 and the device  
shown in Figures 7-10. The closure assembly 222 consists of

5 a closure mechanism 223 and an impervious membrane 224 which covers the closure mechanism 223. The closure mechanism 223 can be formed of the same super-elastic or shape memory material as the closure mechanism 34 but rather than having a coil-like configuration it consists of a plurality of  
10 circumferentially spaced apart rod-like elements 226 or arms of at least three in number having proximal and distal ends 227 and 228. Thus each rod-like element 226 can be similarly formed of Nitinol ribbon or wire and is annealed with an approximate 180 degree fold located at the midpoint  
15 229 between the proximal 227 and distal 228 ends so that when in a free state the element 226 tends to fold at the midpoint 229 causing the proximal and distal halves 231 and 232 of the rod-like element 226 to substantially overlies one another in a single plane. Means is provided to secure the  
20 proximal end 227 of each rod-like element 226 to the deployment mechanism 230 in a manner hereinafter described. The distal ends 228 of the rod-like elements 226 are fastened together in a suitable manner such as by welding or soldering to provide a generally hemispherical tip 233 which  
25 is also secured to the deployment mechanism 230 in a manner hereinafter described. Similar to the closure device 151 shown in Figures 7-10, the lengths and number of the rod-like elements 226 may be selected to correspond to a selected diameter and shape of the closure mechanism 223.

30 The membrane 224 which forms a part of the closure assembly 222 can be formed of the same material as the membrane 36 and can be secured in the same manner to the tubular member 22 so that it is provided with folds and functions in the same manner as the membrane 36.

35 The deployment mechanism 230 consists of a push-pull wire 234 formed of a suitable material such as stainless

5 steel which is slidably disposed in the first or main lumen  
26 and has proximal and distal extremities 236 and 237  
similar to the push-pull wire 41 with the principal  
difference being that during formation the push-pull wire  
234 is provided with a central lumen or bore 238 extending  
10 from the proximal extremity 236 to the distal extremity 237.  
The push-pull wire 234 has a suitable outside diameter of  
approximately .020" (.5 millimeters) and an inside diameter  
of approximately .010" (.25 millimeters). Means is provided  
for circumferentially securing the proximal ends 227 of the  
15 rod-like elements 226 to the distal extremity 237 of the  
push-pull wire 234 with the secured proximal ends 227 of the  
elements 226 being equally spaced apart over 360 degrees and  
with the vertex of each midpoint 229 fold directed outwardly  
and consists of similar welds or solder forming joints 239  
20 and 241. The proximal end 236 of the push-pull wire 234  
extends out of the proximal extremity 23 of the flexible  
elongate tubular member 22 and is connected to a handle  
assembly 242 in a manner similar to the device 21. The  
deployment mechanism 230 includes a second, smaller pull  
25 wire 243 which is slidably mounted or disposed within the  
central lumen 238 of the larger push-pull wire 234 and is  
provided with proximal and distal extremities 244 and 246.  
The pull wire 243 is similarly formed of a suitable material  
such as stainless steel and has a suitable diameter as for  
30 example .005" to .030". Means is provided for securing the  
distal extremity 246 of the pull wire 243 to the hemispheric  
tip 233 and consists of soldering or welding. The proximal  
end 244 of the smaller pull wire 243 also extends out of the  
proximal extremity 23 of the flexible elongate tubular  
35 member 22 and is operatively connected to the handle  
assembly 242 which, in addition to carrying means for



5 causing longitudinal movement of the push-pull wire 234  
hereinbefore described and shown in Figure 1, also carries  
means for causing movement of the pull wire 243 along the  
longitudinal axis independent of the movement of the push-  
pull wire 234 in a manner hereinafter described.

10 The handle assembly 242 is similar to the handle  
assembly 44 with the principal difference being that the  
handle assembly 242 also provides access to the proximal end  
244 of the smaller pull wire 243. The protrusion 247 of  
handle assembly 242 and means of securing the push-pull wire  
15 234 to the same is similar to protrusion 48 but the  
protrusion 247 is also provided with a lumen 248 extending  
from the proximal end 249 to the distal end 251 of the  
protrusion 247 and aligned with the central lumen 238 of the  
proximal extremity 236 of the push-pull wire 234. A handle  
20 lumen 250 is provided which extends proximally from the  
proximal end of the handle slot 255 and is alignment with  
both the slot 255 and the proximal end 249 of the lumen 248  
in the protrusion 247. The handle lumen 250 is provided  
with an aperture 252 at the proximal end of the handle 242.  
25 The proximal end 244 of the smaller pull wire 243 extends  
proximally out of the proximal end 236 of the push-pull wire  
234 into and through the lumen 248 of the protrusion 247 and  
through the handle lumen 250 slidably extending proximally  
out of the handle assembly 242 through the aperture 252.  
30 Means for fixing the proximal end 244 of the pull wire 243  
in a particular position is provided as for example with a  
simple releasable clamp or knob 253 that prevents the pull  
wire 243 from sliding distally.

35 Operation and use of the closure device 221 may now be  
briefly described as follows. It should be appreciated that  
operative positions of the button 254 for operation and use

5 of the closure device 221 are similar to positions for  
button 47 in the closure device 21 shown in Figure 1. A  
closure device 221 can be introduced into the sheath 111 in  
the un-expanded cylindrical or de-deployed configuration  
shown in Figure 15 in the manner hereinbefore described with  
10 respect to the device 21. The closure assembly 222 also can  
be deployed and de-deployed in a similar manner with the  
principal difference being the additional steps of deploying  
and de-deploying the pull wire 243 in a manner hereinafter  
described. After the button 254 is similarly utilized to  
15 initiate and maintain deployment of the closure assembly 222  
by pushing the closure mechanism 223 out of the distal  
extremity 24 of the flexible elongate tubular member 22, the  
rod-like elements 226 and the membrane 224 assume a  
configuration which is substantially in the form of a disk  
20 or a flattened circle, the shape being partially determined  
by the number of the rod-like elements 226. In order to  
assure assumption of a substantially flat planar  
configuration by the closure assembly 222 the small pull  
wire 243 is then pulled proximally and fixed in position by  
25 using the clamp 253, while the push-pull wire 234 is held  
stationary, to cause a pulling force to be applied to the  
hemispherical tip 233 to cause a pushing force to be applied  
to the rod-like elements 226 to cause them to further fold  
about their midpoints 229 so that the proximal and distal  
30 halves 231 and 232 of the elements 226 substantially overlies  
one another in a single plane at a substantially right angle  
to the longitudinal axis of the flexible elongate tubular  
member 22. Thereafter the procedure hereinbefore described  
can be used for establishing a seal of the puncture 106 and  
35 to permit introduction of the biological sealant. After  
this procedure has been completed, the closure assembly 222

5 can be de-deployed by releasing the clamp 253, permitting  
the small pull wire 243 to be pushed distally and then  
similarly completing the de-deployment sequence as  
hereinbefore described for closure device 21.

10 It should be appreciated that additional variations of  
the pull wire assembly may be utilized as for example means  
may be provided for mounting the pull wire within the lumen  
of the push-pull wire so that the position of the pull wire  
is fixed in relation to the longitudinal axis of the  
flexible elongate tubular member so that with independent  
15 longitudinal movement of the push-pull wire a similar  
pulling force is simultaneously applied to the hemispherical  
tip to cause a pushing force to be applied to the rod-like  
elements as hereinbefore described.

20 It should also be appreciated that other embodiments  
may incorporate closure assemblies utilizing arcuate  
segments similar to those shown in Figures 11, 12 and 13,  
absent rod-like elements wherein the distal tip of the push-  
pull wire is bonded directly to the tip of the distal  
extremity of the flexible elongate tubular member so that  
25 with proximal traction on the push-pull wire compressive  
forces applied to the arcuate segments cause outward bowing  
of the same with bends or folds occurring at the midpoints  
of the segments. An additional closure assembly may include  
a closure mechanism constructed of super-elastic or shape  
30 memory alloy that is deployed by pushing the closure  
mechanism distally out of the distal extremity of the  
flexible tubular member and then causing the super-elastic  
or shape memory alloy mechanism to be twisted by turning the  
proximal end of the push-pull wire. In various embodiments  
35 the impermeable membrane may also be secured directly to the  
closure mechanism instead of being secured to the distal

5 extremity of the flexible elongate tubular member.  
Alternatively the membrane may be configured so to only  
partially cover the closure mechanism as for example only  
the proximal side of the deployed closure mechanism.

Another embodiment of an expansile or closure device  
10 incorporating the present invention is shown in Figures 18-  
19. The device 301 shown therein consists of a first  
elongate tubular member 302, preferably a flexible elongate  
tubular member 302, formed of a suitable plastic material,  
preferably a cast thermoset material such as polyimide. The  
15 first flexible elongate tubular member 302 has proximal and  
distal extremities 303 and 304 with a longitudinal axis  
extending from the proximal 303 to the distal extremity 304  
and is provided with a first lumen 306 circular in cross-  
section which, as shown, may be centrally disposed extending  
20 from the proximal extremity 303 to the distal extremity 304.  
Both the outer and inner surfaces of the polyimide member  
302 may be coated with a lubricious material such as  
Teflon™. Alternatively, the thermoset material may be a  
polyimide-Teflon™ or polyimide-Nylon-Teflon™ composite in  
25 order to provide the desired lubricious inner and outer  
surfaces. The first flexible elongate tubular member 302  
has an outside diameter ranging from approximately .008" to  
.050", preferably approximately .018". The first flexible  
elongate tubular member 302 has a suitable length as for  
30 example 10-150 centimeters. The first lumen 306 in the  
first flexible elongate tubular member 302 may have an  
inside diameter of approximately .003" to .030", preferably  
.012".

Expansile means in the form of an expansile assembly  
35 307 is carried by the distal extremity 304 of the first  
flexible elongate tubular member 302 and is movable between

5 contracted and expanded positions. A deployment mechanism 308 is carried by the proximal extremity 303 of the first flexible elongate tubular member 302 and adapted to be operated by the human hand for movement from a contracted position to an expanded or deployed position.

10 The assembly 307 includes a expansile member 309 and a membrane 311 which covers the expansile member 309. The expansile member 309 as shown in Figure 19 is in a form having a complex geometrical configuration, preferably a helical coil configuration 312, when in a free state. The  
15 helical coil 312 is formed of a suitable material, preferably Nitinol, which can be elongated or constrained without permanent deformation but, at body temperature, when freed or unconstrained returns to the helical coil configuration to which it has been annealed. The helical  
20 coil 312 has a plurality of generally circular turns creating, preferably, a proximal turn 313, a middle turn 314 and a distal turn 316. The proximal, middle and distal turns 313, 314, 316 are generally nonplanar with respect to one another. The proximal and distal turns 313 and 316 each  
25 lie in a plane that is generally parallel to one another and generally perpendicular to the longitudinal axis of the first flexible elongate tubular member 302. The middle turn 314 is non-planar and helical as it connects the proximal and distal turns 313 and 316 so that the unconstrained  
30 helical coil configuration assumes a bi-conical shape.

The middle turn 313, when freed or unconstrained, has a suitable diameter ranging from 2 to 10 millimeters and preferably 4 to 6 millimeters is used. As hereinafter described, during deployment the middle turn 313 is  
35 partially flattened and constrained by the membrane 311 to assume a diameter ranging from 1 to 10 millimeters,

5 preferably 11 French, in order to overlap a puncture site to  
assist in occluding the puncture site. The proximal and  
distal turns 313 and 316 are of approximately equal size and  
diameter ranging from 1 to 5 millimeters, preferably 2 to 3  
millimeters. The unconstrained helical coil 312  
10 configuration has a distance from the proximal 313 to the  
distal turns 316 of approximately 3 to 15 millimeters,  
preferably 5 to 8 millimeters. In the de-deployed  
configuration the helical coil 312 is retracted into the  
first flexible elongate tubular member 302 and has a  
15 contracted, constrained diameter corresponding to the  
approximate diameter of the Nitinol wire used to construct  
the expansile mechanism 309, ranging from 0.002" to 0.010",  
preferably .005" to .006". The distal tip of the Nitinol  
wire corresponding to the free end of the distal turn 316,  
20 preferably, carries an enlargement, as for example a small  
ball or flattened tip 310 so as to prevent puncture of the  
membrane 311 by the wire during operation of the device and  
so as to decrease friction of the tip 310 against the wall  
of the lumen 306 of the first flexible elongate tubular  
25 member 302 out of which the expansile mechanism 309 is  
pushed as hereinafter discussed. The ball 310 may be formed  
by a suitable method such as arc welding, soldering,  
applying a polymer to the wire or folding the tip of the  
wire.

30 The deployment means or mechanism 308 includes a push-  
pull element or member 317 preferably in the form of a wire  
317, with proximal and distal extremities 318 and 319 which  
is slidably disposed in and extending through the first or  
main lumen 306. The push-pull element 317 is formed of a  
35 suitable material such as stainless steel and has a suitable  
diameter as for example from .005" to .030", preferably

5 .010". The expansile member 309 and the push-pull element  
317 may be separately constructed and subsequently joined  
together utilizing one of several different methods. The  
two may be bonded or soldered together. Preferably, in  
order to provide for optimal torque, the stainless steel  
10 wire 317 is ground to provide a tapered portion 317a formed  
on the distal end 319. The tapered portion 317a is inserted  
into one end of an elongate member, often called a hypotube  
320 made of an appropriate material such as stainless steel  
and adhesively bonded therein using an appropriate adhesive  
15 325 such as Loctite™. The proximal end 318 of the Nitinol  
wire expansile member 309 is similarly inserted and bonded  
into the opposite end of the hypotube 320. The stainless  
steel hypotube 320 may be of an appropriate length, such as  
from 2 to 15 cm, preferably 4.5 cm. It may have an outer  
20 diameter ranging from .005" to .030", preferably .010" and  
an inner diameter ranging from .003" to .010", preferably  
.006".

Alternatively, both the push-pull wire 317 and the  
expansile mechanism 309 can be formed from a single piece of  
25 Nitinol wire in which case, in order to provide optimal  
pushability, torquability and column strength of the push-  
pull wire 317, two alternative techniques are utilized.  
First, a Nitinol wire diameter of approximately .010" is  
used by grinding down the distal end 319 to a diameter  
30 suitable for subsequent formation of the expansile member  
309.

A second technique utilizes a Nitinol wire having a  
diameter suitable for formation of the expansile mechanism  
309. In such case, the push-pull wire 317 is covered with a  
35 suitable polymer jacket, preferably made of polyimide and  
having an diameter of approximately .005" to .0101". The

5 polymer jacket is thicker at the proximal end 318, necked down at the distal end 319 of the push-pull wire 317 and secured to the push-pull wire 317 at distal and proximal ends by a suitable adhesive such as Loctite™.

10 As shown in Figure 18 the proximal end 318 of the push-pull wire 317 extends out of the proximal extremity 303 of the first flexible elongate tubular member 302 so that the deployment means can be operated by the human hand as hereinafter described.

15 It should also be appreciated that push-pull elements or mechanisms, other than a push-pull wire, can be utilized to deploy and de-deploy the expansile member and the expansile assembly.

20 A stop mechanism or means 321 is provided to control the range of movement or travel of the push-pull wire 317 during deployment and de-deployment of the expansile assembly 307. The stop mechanism 321 comprises first and second, slidable nested or coaxially mounted stop tubes 322 and 323 formed of an appropriate material such as plastic or stainless steel. The distal end of the first stop tube 322 carries a bushing 324. The bushing 324 is secured to the distal end of the first stop tube 322 by suitable means such as an adhesive (not shown). The proximal end 318 of the push-pull element 317 is affixed to the first tube by suitable means such as an adhesive. The push-pull element 30 317 with the first tube 322 affixed thereto and the bushing 324 carried thereby is movable longitudinally of the second tube 323 which has its distal extremity secured to the proximal extremity 303 of the elongate tubular member 302. It is movable from a forward most position with the bushing 35 324 in engagement with the proximal end 303 and a rearwardmost position in engagement with an annulus 326



5 mounted in the proximal extremity of the second tube 323 by  
suitable means such as an adhesive and through which the  
first tube 322 slidably extends. The lengths of the first  
and second tubes 322 and 323 are selected so that the travel  
10 between the forwardmost and rearwardmost positions ranges  
between 2 cm and 10 cm.

The expansile assembly 307 also includes a deformable,  
flexible membrane 311 which is carried by, and as shown, can  
be secured to the distal extremity 304 of the first flexible  
elongate tubular member 302 as hereinafter discussed. Since  
15 it is desired that this membrane 311 be very flexible it has  
a wall thickness ranging from 0.001" to 0.015" and  
preferably about 0.004". It can be formed of any suitable  
flexible material such as an elastomeric or a non-  
elastomeric material including latex and silicone. The  
20 membrane 311 can also be made of an impermeable or a  
permeable material providing for multiple uses of the  
device. A satisfactory membrane 311 can be made of  
Chemoprene™ or one of the polyurethane elastomers such as  
Polyblend™ having a shore hardness durometer of 30 to 70A,  
25 and preferably 55A, Tecoflex™ having a shore hardness  
durometer of 60 to 100A or Pellathane™ having a shore  
hardness durometer of 70 to 100A. Alternatively the  
membrane 311 can be made of multiple layers including a  
central Polyblend™ layer having a thickness of approximately  
30 .005" to .010" and a thin outer Tecoflex™ layer having a  
thickness of approximately .0005". This layered membrane  
311 is made by dipping the Polyblend™ in a Tecoflex™  
solution, for example a Tecoflex™ 85A solution. As shown,  
the membrane 311 is substantially impermeable to blood and  
35 other liquids. It is formed as a tubular sock 333 which has

5 an elongate generally cylindrical configuration with one closed end 329 and the other end circumscribed by an opening 331 which is defined by a rim 332 of the same material. The tubular sock 333 has an appropriate length, as for example ranging from 2-15 mm, preferably 7 mm. When the membrane  
10 311 is made from Polyblend™, typically supplied in a tubular form and cut into lengths of appropriate dimensions with both ends open, the closed end 329 of the membrane 311 is formed by dipping one open end of the Polyblend™ into a Tecoflex™ solution, preferably 10% by weight of 85A  
15 Tecoflex™, to provide a sealing plug 327. The rim 332 of the membrane 311 can be circumferentially secured to the distal extremity 304 of the first flexible elongate tubular member 302 in a suitable manner such as by the Loctite 454™ adhesive (not shown).

20 A length of stainless steel hypotube 328 has one end secured to the distal end 304 of the first flexible elongate tubular member 302 (see Figure 18) using an appropriate adhesive such as Loctite 406™. The hypotube 328 has an appropriate length ranging from 2 mm to 10 mm, preferably 5  
25 mm, and is secured to the first flexible elongate tubular member 302 and extends distally of the same by approximately 2-8 mm. The rim 332 of the membrane 311 is affixed exteriorly of the stainless steel hypotube 328 by an adhesive (not shown), preferably, distal to the point at  
30 which the hypotube 328 is secured to the first flexible elongate tubular member 302 and with the closed end 329 of the membrane 311 oriented distally thereon as shown in Figure 18. As such, a portion of the membrane 311 distal to the rim 332 overlies the steel hypotube 328 and is non-  
35 adherent thereto. It should be appreciated if desired that

5 the rim 332 can be secured directly to the outer surface of  
the distal extremity 304. In either arrangement, the  
membrane 311 assumes a sock-like conformation as shown in  
Figure 18. Alternatively, the rim 332 of the membrane 311  
may be secured interiorly within the hypotube 328 or, if the  
10 hypotube 328 is not utilized, within the first or main lumen  
306 of the first flexible elongate tubular member 302. In  
addition, the membrane 311 may be secured to the Nitinol  
wire proximal to the expansile member 309.

The impermeable membrane 311 of the expansile assembly  
15 307 can be caused to assume various configurations including  
a planar disk-like configuration as shown by the dotted-line  
position in Figure 18. This is accomplished by operation of  
the deployment mechanism 308 to move the push-pull element  
317 distally to urge the expansile member 309 distally out  
20 of the lumen 306 into the membrane 311. The operator can  
assist deployment by applying a slight rotation to the push-  
pull element 317 as it is moved distally. As soon as the  
expansile member 309 clears the first lumen 306, it begins  
to expand into its shape memory, predetermined  
25 configuration. The distal turn 316 of the expansile member  
309 in the form of a coil operates to expand the membrane  
311 initially to a small degree. This initial process  
avoids sudden gross distortion of the membrane 311. As the  
expansile member 309 moves distally out of the lumen 306 and  
30 expands into the membrane 311, the non-adherent portion of  
the membrane 311 distal to the rim 332 preferentially begins  
to move and assume the planar configuration because of the  
lubricious surface of the stainless steel hypotube 328.  
Expansion proceeds with the middle turn 314 forming a coil  
35 and causing the membrane 311 to expand to its desired size,  
approximately 12 French. The proximal turn 313 forming a

5 coil then centralizes and stabilizes the configuration so  
that the push-pull element 317 is centered with respect to  
the middle turn 314 and the fully expanded membrane 334.  
During expansion of the expansile member 309 the membrane  
311 covering the coil 312 constrains the coil 312, thus  
10 exerting counteractive or countervailing contractile forces  
on the expanding coil 312 which is seeking its memorized,  
bi-conical, free shape or configuration 312. Thus, the  
membrane 311 does not expand passively. Rather, the  
expanding coil 312 forcibly expands the membrane 311 to  
15 cause the non-planar turns 313, 314 and 316 of the coil 312  
to assume a substantially planar or disk-like configuration  
with the membrane 334 being taut and disposed on opposite  
sides of the expansile mechanism 309 to form an expansile  
assembly 307 which when expanded is generally perpendicular  
20 to the longitudinal axis of the first flexible elongate  
tubular member 302. The expansile mechanism 309 when  
deployed is sufficiently rigid so as to provide a supporting  
framework for the membrane 311 to keep it taut.

It should be appreciated that other embodiments may be  
25 utilized employing superelastic expansile members with  
various memorized configurations. In addition, as  
hereinbefore discussed, different membrane materials may be  
utilized in order to construct permeable or impermeable  
assemblies for different functions. The predictability of  
30 countervailing, expansile forces and resistive, membrane  
forces enables the construction of expansile assemblies with  
predetermined, deployed configurations. In addition,  
instead of sliding a push-pull wire, the Nitinol member can  
be secured to a wire which remains stationary. In such an  
35 embodiment, the expansile member and wire are sheathed  
within an elongate tubular member which has a sock-like

5 membrane secured to the distal end thereof and whence the member is deployed into the membrane by sliding the sheath proximally.

Operation and use of the device 301 is very similar to that described for the embodiment of the closure device 21  
10 with the following differences. The expansile device 301 shown in Figures 18-19 is not used with biological sealants. Thus, after bringing the expansile assembly 307 into contact with the distal end of the puncture 106, a proximal force of tension or traction is maintained on the expansile assembly  
15 307 for a predetermined period of time ranging from 2 minutes to several hours, preferably 30 minutes to 1 hour, until the puncture 106 is sealed. Release of the tension is followed by moving the expansile assembly 307 from the deployed or expanded position to the de-deployed or  
20 contracted position after which the device 301 may be removed as hereinbefore described.

A second difference is that the radio-opacity of the expansile mechanism 309 is determined by the configuration of the coil 312. When it is in the unconstrained,  
25 memorized, bi-conical configuration, the coil 312 is not fluoroscopically visible due to the small size of the individual turns of the Nitinol wire and the non-planar configuration. When the expansile mechanism 309 assumes the flat disk-like shape within the membrane 334 the cumulative  
30 densities of the Nitinol turns can be fluoroscopically visualized. As hereinbefore discussed, this too is an easy method of ascertaining or confirming formation of a good seal between the expansile assembly 307 and the wall 103 of the vessel 107.

35 Furthermore, the low profile of the device 301 affords the ability to reenter the vessel 107 with the introducer

5 sheath 111 if there has been inadequate occlusion and  
bleeding continues or other complications ensue. For  
example, let it be assumed that the operator believes the  
puncture 106 is sealed after removal of the sheath 111 and  
he therefore de-deploys the expansile assembly 307 as  
10 hereinbefore described. If, after so doing, he observes  
continued bleeding from the puncture 106, the operator can  
reenter the vessel 107 by releasing tension, pushing the  
first flexible elongate tubular member 302 distally and  
reinserting the sheath 111 into the vessel 107 over the  
15 first flexible elongate tubular member 302. The operator  
can also reenter the vessel for additional medical purposes  
if necessary. The same approach applies if the membrane 311  
breaks or the expansile assembly 307 otherwise malfunctions.  
In this case the sheath 111 is replaced as hereinbefore  
20 described and the malfunctioning expansile device 301 is  
expeditiously replaced.

A tension applicator or catheter retention means 335 is  
provided which engages the elongate tubular member 302 and  
serves to releasably place tensioning forces on the elongate  
25 tubular member 302 to maintain engagement of the deployed  
expansile assembly 307 against the vessel wall 103 having a  
puncture 106 therein and to free the operator's hands from  
having to hold the device 301 after it is correctly deployed  
in the puncture 106. The catheter retention means 335  
30 provides a predetermined and substantially constant force in  
a proximal direction on the expansile member 309 over a  
range of motion or positions of the flexible elongate  
tubular member 302 which may occur as a result of patient  
movement or initial positioning.

35 The tensioning device 335 is shown in Figures 20-23 and  
consists of a fixture 336 or bottom portion which is

5 constructed of a suitable material such as clear plastic and  
comprises a base plate 337 having an appropriate shape and  
size, as by way of example a pear-shape and size, as shown  
in Figure 20 and adapted to rest on the skin 101 overlying  
the puncture 106 in the wall 103 forming the lumen 107. The  
10 fixture 336 further comprises anterior and posterior walls  
338 and 339 which extend upwardly, preferably at  
approximately right angles from the surface of the base  
plate 337. The posterior wall 339 has an outer face 342  
that is straight and an inner face 343 that is inclined.  
15 The anterior wall 338 also has inner and outer faces 344 and  
346 that are straight. A swingable arm or top portion 347  
is hingedly or pivotally mounted to the top of the posterior  
wall 339 of the base portion 336 for movement between open  
and closed positions with respect to the base portion 336.  
20 In the open position, the top portion 347 may assume an  
angle of up to 180 degrees, preferably 45 degrees, with  
respect to the base portion 336. In the neutral or closed  
position, the top portion 347 substantially overlies and is  
parallel to the base portion 337. As hereinafter described  
25 however, in the closed position, the top portion 347 is also  
capable of at least .5 cm of additional travel or motion in  
both closed and open directions, both towards and away from  
the base portion 336, respectively.

The arm 347 is hinged and biased or yieldably urged  
30 towards the open position, away from the skin of the  
patient, by spring means capable of providing a  
predetermined and substantially constant tensioning force  
over a range of positions. The top and bottom portions 347  
and 336 of the tensioning device 335 can be constructed as  
35 one piece which incorporates a living hinge 348 formed by  
scoring or placing a groove in the plastic. Alternatively,

5 a metal or other hinge can be utilized to join separate top  
and bottom portions. A constant force spring, such as a  
coil spring 349 capable of providing an appropriate constant  
force of tension is preferably utilized as hereinbefore  
discussed. It should be appreciated that any type of spring  
10 capable of providing the aforementioned constant force of  
tension can be used, as, by way of example, flat, leaf,  
spiral, helical, disk and volute springs.

As shown in Figure 20, catheter clamping or grasping  
means in the form of grasping members 351 are carried by the  
15 arm 347 and are movable between open or release, and closed  
or clamping positions. The grasping members 351 are in the  
form of serrated pads constructed of an appropriate  
material, such as plastic, rubber or metal. The grasping  
members 351 are carried by the distal extremities of  
20 flexible elongate curved spring members or grasping arms  
352. The arms 352 may be constructed of a suitable spring  
material such as plastic or metal and are disposed in a  
recess 350 of the casing of the top portion 347. The  
proximal extremities of the spring arms 352 are disposed on  
25 opposite sides of spaced apart pins 352 mounted so that the  
proximal extremities are biased towards each other into the  
clamping position.

Means are provided for overcoming the bias of the  
spring arms 352 and consists of flanged actuator buttons 354  
30 slidably mounted in holes. Actuator arms 355 are secured to  
the buttons 354 and extend one behind the other to engage  
the opposite spring arm 352 (see Figure 21) so that the  
spring arms 352 can be moved apart to move the grasping  
members 351 to the open position.

35 The fixture and arm portions 337 and 347 may be formed  
with slots 356 and 357 which are in alignment when the arm



5 347 is in the closed position and in which the first elongate tubular member 302 or body 362 is disposed when being grasped by the grasping members 351.

Operation of the tension applicator 335 may now be described in conjunction with Figures 21-23. By placing the  
10 fixture 336 against the patient's skin and, as shown in Figures 22-23, urging or forcing the arm 347 towards the fixture 336 until it comes into apposition with the base plate 337 and opening the spring arms 352 in order to grasp the first flexible elongate tubular member 302 or elongate  
15 tubular body 362, the tensioning device 335 can be set or activated whence it maintains a suitable, constant proximal force of tension, preferably within a range of .25 to 3 pounds, over a range of motion. The force applied to the first flexible elongate tubular member 302 attempts to  
20 withdraw the member 302 from the puncture 106 in the wall 103 of the vessel 107 so that the expansile device 302 is retained in engagement with the wall 103 of the vessel 107.

Indicator marks in the form of arrows 358 are placed on the fixture 336 and the arm 347 so that the marks are  
25 aligned with one another when the tensioning means 335 is correctly positioned and activated in the neutral, closed position as hereinbefore described. Alternatively, visualization through the clear plastic base plate 337 can serve as indicator means.

30 It should be appreciated that other embodiments of the tension applicator or tensioning device may be utilized in the present invention without departing from the novelty and the intended uses thereof. For example, the grasping means can be comprised of asymmetrical members and arms, similar  
35 to a pin vise or clamp. In such an embodiment one grasping arm is slidably disposed within another and can be spring

5 loaded or otherwise biased into a position in which one grasping member is apposed with the other grasping member. Alternatively, two grasping arms may be constructed from a single arm which has been partially split along its longitudinal axis, providing arms that splay apart.

10 Grasping members may also be comprised of clamps that snap or roll into closed positions. Similarly, the arm may have a length that is shorter than the bottom portion and beyond which the grasping members and arms extend. It should also be appreciated that the tension applicator 335 can be used  
15 with other catheters.

The tensioning device 335 with its indicators also serve to confirm formation of a good, occlusive seal of the puncture 106 with the expansile assembly 307. The deployed  
20 expansile assembly 307 withstands the aforementioned proximal force or tension and in so doing maintains the occlusive seal unless the deployed coil 312 and disk-shaped membrane 334 change configurations. For example, if the  
25 membrane 311 breaks, the coil 312 once again assumes its memorized bi-conical configuration 312 which cannot maintain a high tensile force and is incompatible with puncture occlusion. As tension is lost the indicator on the  
30 tensioning device 335 is activated, alerting the operator to the release of the predetermined force of tension and lack of an adequate seal.

30 Another embodiment of the expansile device is shown in Figure 24. The expansile device 360 is very similar to that shown in Figure 18 with the principal difference being that, in addition, it provides means for introducing a biological  
35 sealant into the puncture proximal to the expansile mechanism to seal the puncture. Thus all the parts of the expansile device 301 that are present in the expansile

5 device 360 carry the same numbers. The biological sealant  
introducer means 361 is carried by a flexible elongate  
tubular body 362 comprising first and second flexible  
elongate tubular members 302 and 363. The first flexible  
elongate tubular member 302 is as hereinbefore described.  
10 The second flexible elongate tubular member 363 is formed of  
suitable plastic material, preferably an extruded  
thermoplastic elastomer such as Pebax™ having a shore  
hardness durometer of 50D or 72D. The second flexible  
elongate tubular member 363 has proximal and distal  
15 extremities 364 and 366, extends along a longitudinal axis  
and has an inner wall 367 defining a lumen 368 extending  
from the proximal 364 to the distal extremity 366. The  
lumen 368 has a diameter greater than the outer diameter of  
the first flexible elongate tubular member 302. The first  
20 flexible elongate tubular member 302 is disposed or nested  
within the lumen 368 of the second flexible elongate tubular  
member 363 thereby defining a first, circumferential or  
annular space 369 between the outer surface of the first  
flexible elongate tubular member 302 and the inner wall 367  
25 of the second flexible elongate tubular member 363. The  
distal extremity 366 of the second flexible elongate tubular  
member 363 terminates proximal to the distal extremity 304  
of the first flexible elongate tubular member 302 and  
adjacent to the expansile mechanism 309.

30 The second flexible elongate tubular member 363 is of a  
suitable size, as for example an outer diameter ranging from  
.020" to .050", an inner or lumen diameter ranging from  
.015" to .040" and has a suitable length as for example 10-  
160 centimeters. As hereinbefore discussed, the distal  
35 extremity 366 of the second flexible elongate tubular member  
363 terminates proximal to the distal extremity 304 of the

5 first flexible elongate tubular member 302 and adjacent to the expansile mechanism 309, as for example 1-15 millimeters up to several centimeters proximal.

Proximal adaption for sealant introduction into the flexible elongate tubular body 362 includes appropriate tee or wye adapters. Preferably, as shown in Figure 24, a tee adapter 375 has one end fixed to the proximal extremity 364 of the second flexible elongate tubular member 363 using a suitable adhesive. The second end of the tee adapter 375 carries a compression fitting 376 in order to accommodate the proximal end 303 of the first flexible elongate tubular member 302 which is disposed within and extends proximally out of the tee adapter 375. The compression fitting 376 provides a leakproof connection between the first and second flexible elongate tubular members 302 and 363 and enables removal of the second flexible elongate tubular member 363 while the first flexible elongate tubular member 302 is maintained in the deployed position. Introduction of sealants is accomplished via a fluid port 377 which communicates with the proximal end 364 of the second flexible elongate tubular member 363 as shown in Figure 22. An alignment window 378 in the tee adapter 375 is provided which is used to visually align a marker 379 on the proximal extremity 303 of the first flexible elongate tubular member 302 or on the proximal extremity 318 of the push-pull wire 317 so that the distal extremity 366 of the second flexible elongate tubular member 363 is appropriately positioned proximal to the distal extremity 304 of the first flexible elongate tubular member 302 and adjacent to the expansile mechanism 309 as hereinbefore described.

35 Operation and use of the device 360 is similar to that described for the expansile device 301 except for the

5 ability to introduce biological sealants with the device  
360. As soon as it has been established that a good seal  
has been formed between the occlusion assembly 307 and the  
wall 103 adjacent the puncture the operator can introduce  
the constituents of the biological sealant into the fluid  
10 port 377 of the adapter 375 hereinbefore described. The  
sealant is then introduced into the proximal end 364 of the  
second flexible elongate tubular member 363 into the first  
space 369 between the outer surface of the first flexible  
elongate tubular member 302 and the inner wall 367 of the  
15 second flexible elongate tubular member 363, thence exiting  
proximal to the distal extremity 304 of the first flexible  
elongate tubular member 302 and adjacent to the expansile  
mechanism 309. The remainder of the operation of the device  
360 is as hereinbefore described in conjunction with the use  
20 of the device 21 and the device 301.

Another embodiment of a expansile device incorporating  
the present invention is shown in Figures 25-26. The  
expansile device 401 is very similar to that shown in Figure  
24 with the principal difference being in the biological  
25 sealant means utilized in the device 401. Thus all of the  
parts of the expansile device 360 that are present in the  
expansile device 401 carry the same numbers. The biological  
sealant means 402 is also similar to that shown in Figure 24  
with the principal difference being that the flexible  
30 elongate tubular body 362 further includes a third flexible  
elongate tubular member 403 formed of suitable plastic  
material, also preferably an extruded thermoplastic  
elastomer such as Pebax™ having a durometer of 63D or 72D.  
The third flexible elongate tubular member 403 has proximal  
35 and distal extremities 404 and 406, extends along a  
longitudinal axis and has an inner wall 407 defining a lumen

5 408 extending from the proximal 404 to distal extremity 406  
and having a diameter greater than the outer diameter of the  
second flexible elongate tubular member 363. The second  
flexible elongate tubular member 363 is nested or disposed  
10 within the lumen 408 of the third flexible elongate tubular  
member 403 thereby defining a second, circumferential or  
annular space 409 between the second flexible elongate  
tubular member 363 and the inner wall 407 of the third  
flexible elongate tubular member 403. The distal extremity  
15 406 of the third flexible elongate tubular member 403  
terminates distal to the distal extremity 366 of the second  
flexible elongate tubular member 363 and proximal to the  
distal extremity 304 of the first flexible elongate tubular  
member 302 thereby defining an annular distal mixing chamber  
20 411 between the first flexible elongate tubular member 302  
and the inner wall 407 of the third flexible elongate  
tubular member 403.

The third flexible elongate tubular member 403 is of a  
suitable size, as for example an outer diameter ranging from  
.030" to .070", and has a suitable length as for example 10-  
25 160 centimeters. As hereinbefore discussed, the distal  
extremity 406 of the third flexible elongate tubular member  
403 terminates distal to the distal extremity 366 of the  
second flexible elongate tubular member 363, as for example  
from 1-15 millimeters distal, preferably 5 millimeters, thus  
30 creating the distal mixing chamber 411. The distal  
extremity 406 of the third flexible elongate tubular member  
403 also terminates proximal to the distal extremity 304 of  
the first flexible elongate tubular member 302 and adjacent  
to the expansile mechanism 309, as for example 1-15  
35 millimeters up to several centimeters proximal. In order to  
affect this configuration, the second flexible elongate

5 tubular member 363 may be of a suitable length that is slightly shorter than the length of the second flexible elongate tubular member 363 in device 360.

Proximal adaption for sealant introduction into this triple flexible elongate tubular member body is provided so  
10 that either the second flexible elongate tubular member 363 or the second and third flexible elongate tubular members 363 and 403 can be reversibly disengaged and removed. Removing the second flexible elongate tubular member 363 provides access to a larger space between the first and  
15 third flexible elongate tubular members 302 and 403 in order to provide for more reliable aspiration attempts. Removing both the second and third flexible elongate tubular members 363 and 403 provides for use of the isolated expansile device 301 as hereinbefore discussed, and also permits  
20 cleaning of the removed tubular members as necessary.

The proximal adaption for the device 401 includes appropriate tee or wye adapters as hereinbefore described. The proximal adaption 375 for the second flexible elongate tubular member 363 is similar to the proximal adaption 375  
25 for the second flexible elongate tubular member 363 in device 360. The third flexible elongate tubular member 403 carries similar proximal adaption 412 in the form of a tee adapter 412, compression fitting 413 and a fluid port 414 so that, as hereinbefore discussed, the second flexible  
30 elongate tubular member 363 can be disposed or nested within the third flexible elongate tubular member 403 with a proximal seal between the two members that is fluid-tight. A second sealant or component thereof can be introduced into the fluid port 414 of the compression fitting 413 on the  
35 third flexible elongate tubular member 403 as hereinafter discussed.

5           In addition, the proximal adapter 412 of third flexible  
elongate tubular member 403 carries an alignment window 416  
in order to permit the operator to visually align a marker  
417 on the second flexible elongate tubular member 363  
within the window 416 so that during use the second and  
10       third flexible elongate tubular members 363 and 403 are  
appropriately positioned with respect to one another. It  
should be appreciated that second and third flexible  
elongate tubular members 363 and 403 can be constructed as a  
single unit whereby only the unit is capable of being  
15       inserted and removed over the first flexible elongate  
tubular member.

          Operation and use of the device 401 is similar to that  
described for the expansile device 360 except for use of the  
biological sealant means 402 in the device 401. As soon as  
20       it has been established that a good seal has been formed  
between the occlusion assembly 307 and the wall 103 adjacent  
the puncture the physician can introduce the constituents of  
the biological sealant into the fluid port 377 of the  
adapter 375 on the proximal end 364 of the second flexible  
25       elongate tubular member 363 into the first space 369 and  
into the fluid port 414 of the adapter 412 on the proximal  
end 404 of the third flexible elongate tubular member 403  
into the second space 409 respectively, causing the  
constituents to travel separately, distally into the distal  
30       mixing chamber 411 where they are well mixed and whence the  
mixed sealant exits proximal to the distal extremity 304 of  
the first flexible elongate tubular member 302 and adjacent  
to the expansile mechanism 309. The remainder of the  
operation of the device 401 is as hereinbefore described in  
35       conjunction with the use of the device 21.

          Another embodiment of a expansile device incorporating



5 the present invention is shown in Figures 27-30. The  
expansile device 418 is also very similar to that shown in  
Figure 24 with the principal difference being in the  
biological sealant means 419 utilized in the device 418.  
Thus all of the parts of the expansile device 360 that are  
10 present in the expansile device 418 carry the same numbers.

The second flexible elongate tubular member 363 of the  
device 418 is provided with an additional or second lumen  
425 which may be half-circular in cross-section, is  
laterally disposed and also extends from the proximal  
15 extremity 364 to the distal extremity 366 of the second  
flexible elongate tubular member 363 as shown in Figure 27.  
In order for the second flexible elongate tubular member 363  
to carry the second lumen 425, the first lumen 368 may also  
be laterally disposed. The second lumen 425 has a suitable  
20 chord length ranging from .020" to .040".

The second lumen 425 of the device 418 may be utilized  
for introducing biological sealants as hereinbefore  
described in conjunction with the device 360. The second  
lumen 425 can also be used for aspiration attempts, to  
25 verify formation of a good seal between the expansile  
assembly 307 and the wall 103 of the vessel 107 has  
hereinbefore described in conjunction with the device 21.

The expansile device 418 is also provided with a third  
flexible elongate member 430 having proximal and distal  
30 extremities 431 and 432 and extending along a longitudinal  
axis. Shown in Figures 27-28 and Figure 30, the third  
flexible elongate member 430 is sized and shaped to be  
reversibly, frictionally disposed within the second lumen  
425 of the second flexible elongate tubular member 363 and  
35 has a length substantially equal to the length of the second  
flexible elongate tubular member 363.

5           The third flexible elongate member 430 is similarly formed of a suitable plastic material such as Pebax™ and is solid in construction, as shown in Figure 28, so that it functions as an obturator for the second lumen 425 of the second flexible elongate tubular member 363, thus keeping  
10           the same un-obstructed until ready for use.

          There is provided an alternate third flexible elongate member 433 which is similarly sized and shaped and functions as a biological sealant introducer means. As shown in Figures 27 and 30, this alternate third flexible elongate  
15           member 433 carries first and second lumens 434 and 436, each extending from the proximal to the distal extremity 431 and 432 of the alternate third flexible elongate member 433. A mixing chamber 437 contiguous with and created by the distal confluence of the first and second lumens 434 and 436 is  
20           carried by the distal extremity 432 of the third flexible elongate member 433. Alternatively, the third flexible elongate member 433 can be without the aforementioned distal confluence of lumens and, in place thereof, have a length slightly shorter than that of the second flexible elongate  
25           tubular member 363 so that a mixing chamber 437 is created within the distal end 366 of the second flexible elongate tubular member 363.

          Proximal adaption 438 for sealant introduction into this third flexible elongate member 433 is provided as shown  
30           in Figure 27. The proximal extremity 431 of the third flexible elongate member 433 carries a fitting or adapter 438 having two or more fluid ports 439 in alignment with the first and second lumens 434 and 436 of the third flexible elongate member 433. The fitting 438 is constructed out of  
35           a suitable material such as plastic or nylon, by way of example, polycarbonate or Isoplast™, and is bonded to the

5 third flexible elongate member 433 by an appropriate  
adhesive. Alternatively, the adapter 438 can be constructed  
of Pebax™ 82D, and be heat fused to the proximal end 431 of  
the third flexible elongate member 433. It should be  
appreciated that the adapter 438 may be constructed so as to  
10 be reversibly connected to the third flexible elongate  
member 433.

Operation and use of the device 418 is similar to that  
hereinbefore discussed in conjunction with the device 401.  
Constituents of biological sealants are introduced  
15 proximally into the adapter 438 and thence into the first  
and second lumens 434 and 436 causing the constituents to  
travel separately, distally into the distal mixing chamber  
437 where they are well mixed and whence the mixed sealant  
exits proximal to the distal extremity 304 of the first  
20 flexible elongate tubular member 302 and adjacent to the  
expansile mechanism 309.

Alternately, as shown in Figures 31-32, a third  
flexible elongate tubular member 450 is provided which,  
other than being tubular in shape, is similar in  
25 construction to the alternate third flexible elongate  
members hereinbefore discussed. This third flexible  
elongate tubular member 450 is also sized to be frictionally  
disposed within the second lumen 425 of the second flexible  
elongate tubular member 363 in which case the area in the  
30 second lumen 425 of the second flexible elongate tubular  
member 363 surrounding the third flexible elongate tubular  
member 450 is used as a second space 451 into which  
biological sealants are introduced as hereinafter discussed.

Proximal adaption for sealant introduction into the  
35 second lumen 425 of the second flexible elongate tubular  
member 363 and the third flexible elongate tubular member

5 450 is provided as shown in Figure 31. The proximal  
extremity 364 of the second flexible elongate tubular member  
363 carries a fitting or adapter 452 constructed in a manner  
similar to that hereinbefore discussed. The adapter 452 has  
proximal and distal ends 453 and 454 and carries a variably-  
10 shaped lumen 456 extending therethrough. The distal end 454  
of the adapter lumen 456 is sized, configured and aligned  
with the second lumen 425 of the second flexible elongate  
tubular member 363. The proximal end 453 of the adapter  
lumen 456 is circular in cross-section and is sized so as to  
15 frictionally accept the third flexible elongate tubular  
member 450. A fluid port 457 is connected to the adapter  
lumen 456. As shown in Figure 31, the proximal end 431 of  
the third flexible elongate tubular member 450 also carries  
a fluid port 458. The third flexible elongate tubular  
20 member 450 is of a slightly shorter length than that of the  
second flexible elongate tubular member 363 in order to  
create the distal mixing chamber 437 as hereinbefore  
discussed. Operation and use is as hereinbefore described.

Alternatively, instead of utilizing a third flexible  
25 elongate member the second flexible elongate tubular member  
of the expansile device is provided with a third lumen (not  
shown) extending from the proximal to the distal extremity  
and. A mixing chamber contiguous with and created by the  
distal confluence of the second and third lumens and is  
30 carried by the distal extremity of the second flexible  
elongate tubular member. Proximal adaption for sealant  
introduction and a handle assembly can be utilized as  
hereinbefore discussed. Operation and use is as  
hereinbefore described.

35 It is apparent from the foregoing that there has been  
provided an expansile or closure device and method for

5 percutaneous access and occlusion of punctures which medical  
procedures have required being placed in the human body. By  
varying the free shape or configuration of the super elastic  
alloy expansile member and the size and material of the  
membrane, the predetermined configuration and rigidity of  
10 the expansile assembly is varied so that it becomes possible  
to occlude puncture sites and natural tracts of various  
sizes and in various locations in the body such as  
laparoscopic puncture sites, pleural-cutaneous fistulas,  
including chest-tube puncture sites, intestinal-cutaneous  
15 fistulas, fistulas between the intestines, biliary tract of  
the stomach and the like. The expansile assembly  
establishes the distal boundary for the puncture so that it  
enables accurate placement of and prevents inadvertent  
intravascular injection and embolization of the biological  
20 sealant. The expansile device of the present invention  
makes possible the use of biological sealants in which for  
example fibrin glue is utilized and forms a clot which has  
greater strength than a natural clot formed by the body. In  
addition it makes it possible to the bypass the natural  
25 coagulation system of the human body even though  
anticoagulants have been administered to the patient during  
the prior medical procedure or procedures. Although fibrin  
glue has been discussed as the principal biological sealant,  
other sealants may be utilized such as collagen, Avitene™  
30 slurries, Gel Foam™, cellulose, fibrin and thrombin,  
collagen and thrombin mixtures, all of which are non-  
adherent to the expansile device. Individual components of  
multi-component sealants may be separately introduced into  
the different annular spaces of the expansile device  
35 comprising three flexible elongate tubular members. By  
utilizing an annular distal mixing chamber, component-to-

5 component fluid contact is maximized. A maximized area of  
contact affords optimal mixing and setting of the sealant at  
just the site where it is needed. Furthermore,  
circumferential introduction of mixed biological sealant  
into the puncture provides better distribution. In  
10 addition, it should be appreciated that other means of  
sealant introduction to the flexible elongate tubular member  
are available. For example, a multi-component sealant such  
as fibrin glue may, alternatively, be mixed prior to  
introduction into the flexible elongate tubular member.

15 The shape of the expansile mechanism utilized in the  
expansile device of the present invention that abuts the  
inner surface of the wall through which the puncture extends  
enlists the normal pressure of the arterial blood flow to  
help retain the expansile assembly in contact with the wall.  
20 The expansile assembly is small in size and even when being  
deployed into the blood vessel permits substantially  
unobstructed blood flow through the vessel to continue;  
during the expansile procedure thus avoiding ischemic and  
thrombotic complications associated with stasis of blood.  
25 The small size similarly prevents the expansile assembly  
from damaging or impinging on the opposite wall of the blood  
vessel during deployment or de-deployment of the device.

Since the expansile device and method of the present  
invention does not require long term intravascular  
30 deployment of a foreign body such as collagen, intra-  
arterial anchors or sutures, nor does it utilize balloon  
technology with the attendant risks of balloon rupture or  
tearing, there is a greatly reduced risk of life and limb  
threatening infections and the introduction of particulates  
35 or air emboli into the bloodstream.

The catheter retention and tension applicator of the

5 present invention provide a constant force of proximal  
tension on the deployed device. An inherent safety feature  
is the constant force of tension provided over a range of  
motion as hereinbefore discussed. As this obviates the need  
for manual pressure and clamping devices traditionally used,  
10 it frees medical personnel to attend to other duties.

Since the occlusions which are formed in punctures  
utilizing the expansile device and method of the present  
invention can be accomplished quickly, this facilitates  
early ambulation of the patient and helps to avoid  
15 traditional complications such as arterio-venous fistulas,  
pseudo-aneurysms, thrombosis and embolism. Since the device  
is typically disposed of after one use, the danger of  
transmitting diseases to the blood stream of the patient is  
greatly reduced. Medical costs to the patient and to  
20 society are also thereby reduced.

Although the expansile device and method have been  
described principally in use with the human body it should  
be appreciated that the expansile device and method also can  
be utilized with animals in a similar manner.

25 In addition, it should be appreciated that the  
expansile device can be used within other natural tracts in  
the body in order to provide for other therapeutic or  
prophylactic modalities.

It is apparent from the foregoing that there has been  
30 provided a expansile device and method for percutaneous  
access and occlusion of puncture sites in the human body  
that have distinct advantages over those heretofore  
provided.

Percutaneous methods are widespread techniques that  
35 offer less invasive, safer and more cost-effective  
diagnostic and therapeutic access to organs of the human

5 body. In order to fully realize the advantages of  
percutaneous access however, morbidity associated with  
access sites must be anticipated and prevented wherever  
possible. Indeed, advanced therapeutic interventions have  
led to a greater range of access site complications. A  
10 patient who suffers such complications must often undergo a  
more invasive procedure in order to prevent devastating  
injury to life or limb. Such procedures incur additional  
risks and costs. Effective percutaneous occlusion of a  
percutaneous vascular access site that proves to be  
15 otherwise difficult to manage is a major achievement.  
Without such treatment many of the advantages of  
percutaneous diagnostic and therapeutic procedures are lost.  
Satisfactory solutions have heretofore been absent in the  
prior art. The device and method of the present invention  
20 obviate many of the morbid side effects associated with  
puncture sites hereinbefore described.



5    **WHAT IS CLAIMED:**

1. A device for expansion within a blood vessel having a wall defining a lumen in the body comprising a first elongate tubular member having proximal and distal extremities and having a longitudinal axis, an expansile member carried by the distal extremity of the first elongate tubular member and movable between contracted and expanded positions, said expansile member having a predetermined configuration in the expanded position, a deformable membrane covering the expansile member, said deformable membrane being sized so as to be capable of overlying and underlying the expansile member in the expanded position and deployment means carried by the proximal extremity of the first elongate tubular member and adapted to be operated by the human hand for controlling movement of the expansile member between the contracted and expanded positions.

2. A device as in Claim 1 wherein said membrane is sized so as to be capable of expanding relative to the expansile member and constraining the expansile member into said predetermined configuration.

3. A device as in Claim 1 further including tensioning means for maintaining engagement of said expansile member in the expanded position with the wall in the lumen of the blood vessel.

4. A device as in Claim 3 wherein said tensioning means includes a base portion, an arm connected to said base portion and movable between open and closed positions with respect to said base portion, said arm having means for grasping said first elongate tubular member and means for biasing said top portion into the open position.

5. A device as in Claim 4 wherein said means for grasping said first elongate tubular member includes two

5 grasping members carried by said arm, said grasping members being movable between open and closed positions.

6. A device as in Claim 5 wherein said grasping members are formed so as to be biased into said closed position for grasping said first elongate tubular member.

10 7. A device as in Claim 4 further including a first slot in the fixture and a second slot in the arm which is aligned with the first slot when the arm is in the closed position, said first elongate tubular member being disposed in said first and second slots when grasped by said grasping  
15 means.

8. A device as in Claim 4 wherein said means for biasing said arm into the open position includes a spring capable of producing a substantially constant force of tension over a range of motion.

20 9. A device as in Claim 8 wherein said spring is a coil spring.

10. A device as in Claim 1 wherein said expansile member is comprised essentially of a superelastic material and has a configuration in the free state which is a  
25 substantially complex geometrical configuration.

11. A device as in Claim 10 wherein said configuration in a free state is larger than said predetermined configuration.

12. A device as in 10 wherein said membrane is capable  
30 of constraining said expansile member from the free state configuration into said predetermined configuration.

13. A device as in Claim 10 wherein said configuration in a free state is substantially non-planar and said predetermined configuration is substantially planar.

35 14. A device as in Claim 10 wherein said configuration in a free state is a bi-conical coil-like configuration.

5           15. A device as in Claim 14 wherein said coil-like  
configuration includes proximal, middle and distal turns  
which are non-planar with respect to one another, said  
proximal and distal turns being of substantially equal size  
and said middle turn being larger than said proximal and  
10 distal turns.

16. A device as in Claim 1 wherein the membrane has a  
closed end and an open end circumscribed by a rim and means  
for securing the rim to the distal extremity of the first  
elongate tubular member, said membrane being formed to  
15 permit movement of the expansile member within the membrane  
during movement between contracted and expanded positions  
and to constrain said expansile member into its  
predetermined configuration with the membrane being disposed  
on opposite sides of the expansile member.

20           17. A device as in Claim 1 further including means  
connected to said first elongate tubular member for  
introducing a biological sealant into the body proximal to  
said expansile member and external to the lumen of the  
vessel, said introducing means including a second elongate  
25 tubular member having proximal and distal extremities and  
having a longitudinal axis, said second elongate tubular  
member having an inner wall defining a lumen extending from  
the proximal to the distal extremity of said second elongate  
tubular member, said lumen of the second elongate tubular  
30 member having a diameter greater than the outer diameter of  
said first elongate tubular member, said first elongate  
tubular member being disposed within the lumen of said  
second elongate tubular member thereby defining a space  
between said first elongate tubular member and the inner  
35 wall of said second elongate tubular member, the distal  
extremity of said second elongate tubular member terminating

5 proximal to the distal extremity of said first elongate tubular member and adjacent to said expansile member.

18. A device as in Claim 17 wherein said biological sealant is selected from a group consisting of: (a) fibrin glue; (b) collagen; (c) Avitene; (d) cellulose; (e) gelatin;  
10 (f) Gelfoam; (g) thrombin; (h) fibrin; (i) thrombin-collagen.

19. A device as in Claim 17 wherein said second elongate tubular member includes a second lumen extending from the proximal extremity to the distal extremity of the second elongate tubular member.

15 20. A device as in Claim 19 wherein said second elongate tubular member includes a third lumen extending from the proximal extremity to the distal extremity of said second elongate tubular member.

21. A device as in Claim 19 further comprising a third elongate member having proximal and distal extremities and a longitudinal axis, said third elongate member being sized to be reversibly disposed within the second lumen of said;  
20 second elongate member.

22. A device as in Claim 20 wherein the distal extremity of the second elongate tubular member carries a mixing chamber which is contiguous with the second and third lumens of the second elongate tubular member.

23. A device as in Claim 21 wherein said third elongate member has a length substantially equal to the  
30 length of said second elongate member.

24. A device as in Claim 21 wherein said third elongate member has a lumen extending from the proximal to the distal extremity of the third elongate member and wherein the distal extremity of said third elongate member terminates prior to the distal extremity of said second  
35 elongate member.

5           25. A device as in Claim 24 wherein the second lumen of the second elongate tubular member is semi-circular in shape and the third elongate member is tubular in shape.

10           26. A device as in Claim 24 wherein said third elongate member has a second lumen extending from the proximal to the distal extremity of the third elongate member.

15           27. A device as in Claim 26 wherein the distal extremity of the third elongate member carries a mixing chamber which is contiguous with the first and second lumens of the third elongate member.

          28. A device as in Claim 1 wherein said deployment means includes a push-pull member.

          29. A device as in Claim 28 wherein said push-pull member is a wire.

20           30. A device for being expanded within a blood vessel having a wall defining a lumen in the body comprising an elongate tubular body having proximal and distal extremities and having a longitudinal axis, said elongate tubular body further comprising first, second and third elongate tubular members, each of said tubular members having proximal and  
25           distal extremities and a longitudinal axis and having a lumen defining an inner wall and extending from the proximal to the distal extremity of each of said tubular members, the first elongate tubular member having a diameter being sized  
30           so that it can be disposed within the lumen of the second elongate tubular member thereby defining a first space between the first and second elongate tubular members, the second elongate tubular member having a diameter being sized  
35           so that it can be disposed within the lumen of the third elongate tubular member thereby defining a second space between the second and third elongate tubular members, an

5 expansile member carried by the distal end of said elongate  
tubular body and movable between contracted and expanded  
positions, said expansile member having a predetermined  
configuration in the expanded position, a deformable  
membrane covering the expansile member, said deformable  
10 membrane being sized so as to be capable of overlying and  
underlying the expansile member in the expanded position and  
deployment means carried by the proximal extremity of the  
elongate tubular body and adapted to be operated by the  
human hand for controlling movement of the expansile member  
15 between the contracted and expanded positions.

31. A device as in Claim 30 wherein said membrane is  
sized so as to be capable of expanding relative to the  
expansile member and constraining the expansile member into  
said predetermined configuration.

20 32. A device as in Claim 30 further including means  
for reversibly disengaging and removing said second elongate  
tubular member.

33. A device as in Claim 32 further including means  
for reversibly disengaging and removing said third elongate  
25 tubular member.

34. A device as in Claim 30 further including means  
carried by said elongate tubular body for introducing at  
least one biological sealant into the proximal extremity of  
said elongate tubular body into said first and second spaces  
30 so that said sealant is introduced into the body proximal to  
said expansile member and external to said vessel lumen.

35. A device as in Claim 34 wherein the distal  
extremity of said third elongate tubular member terminates  
distal to the distal extremity of said second elongate  
35 tubular member and proximal to the distal extremity of said  
first elongate tubular member thereby defining a distal

5 mixing chamber between said first elongate tubular member  
and the inner wall of said third elongate tubular member.

36. A device as in Claim 30 further including  
tensioning means for maintaining engagement of said  
expansile member in the expanded position with the wall in  
10 the lumen of the blood vessel.

37. A device as in Claim 30 wherein said expansile  
member is comprised essentially of a superelastic material  
and has a configuration in the free state which is a  
substantially complex geometrical configuration.

15 38. A device as in Claim 37 wherein said configuration  
in a free state is a bi-conical coil-like configuration.

39. A device as in Claim 30 wherein the membrane has a  
closed end and an open end circumscribed by a rim and means  
for securing the rim to the distal extremity of the first  
20 elongate tubular member, said membrane being formed to  
permit movement of the expansile member within the membrane  
during movement between contracted and expanded positions  
and to constrain said expansile member into its  
predetermined configuration with the membrane being disposed  
25 on opposite sides of the expansile member.

40. A device for applying tension on a catheter  
extending into a puncture in the wall of the blood vessel  
underlying the skin of a patient, the catheter having  
proximal and distal extremities and an expansile assembly  
30 secured to the distal extremity comprising a fixture having  
a base adapted to rest on the skin of the patient, a movable  
arm pivotally mounted on the base and means mounted on the  
arm for releasably grasping the proximal extremity of the  
catheter and means carried by the base and engaging the arm  
35 to yieldably urge the arm in a direction away from the skin  
of the patient whereby a tensioning force is applied to the

5 catheter to attempt to withdraw the catheter from the  
puncture so that the expansile assembly is retained in  
engagement with the wall of the vessel at the puncture.

41. An device as in Claim 40 wherein the means mounted  
on the arm releasably grasping the proximal end of the  
10 catheter includes first and second grasping members and  
first and second spring members carrying said grasping  
members mounted on said arm and urging the grasping members  
toward a catheter grasping position and means mounted on the  
arm engagable by the hand for overcoming the yieldable force  
15 of the first and second spring members to move the grasping  
members to a catheter release position.

42. An device as in Claim 41 wherein said grasping  
members have serrated surfaces for engaging the catheter.

43. An device as in Claim 40 wherein said means  
20 carried by the base for yieldably urging the arm in a  
direction away from the skin of the patient includes a  
spring.

44. An device as in Claim 43 wherein said spring is a  
constant force spring.

45. A method for percutaneously expanding a device  
within a blood vessel having a wall defining a lumen in the  
human body, by use of a device having a first elongate  
tubular member having proximal and distal extremities and a  
longitudinal axis, an expansile member carried by the distal  
30 extremity of the first elongate tubular member, a deformable  
membrane covering the expansile member, said expansile  
member being movable between contracted and expanded  
positions and said membrane being sized so as to be capable  
of overlying and underlying the expansile member in the  
35 expanded position and deployment means carried by the  
proximal extremity of the of the first elongate member and



5 adapted to be operated by the human hand for controlling  
movement of the expansile member between contracted and  
expanded positions, the method comprising introducing the  
distal extremity of the first elongate tubular member and  
the expansile member carried thereby through the wall of the  
10 vessel so that the expansile member is disposed within the  
lumen of the vessel, moving the expansile assembly from a  
contracted to an expanded position and pulling the first  
elongate tubular member proximally to bring the expansile  
member into engagement with the wall in the lumen of the  
15 vessel.

46. A method as in Claim 45 together with the step of  
applying a predetermined proximal force of tension to the  
expansile member after bringing the expansile member into  
engagement with the wall of the lumen of the vessel and  
20 releasing said tension before moving the expansile member  
from the expanded position to a contracted position.

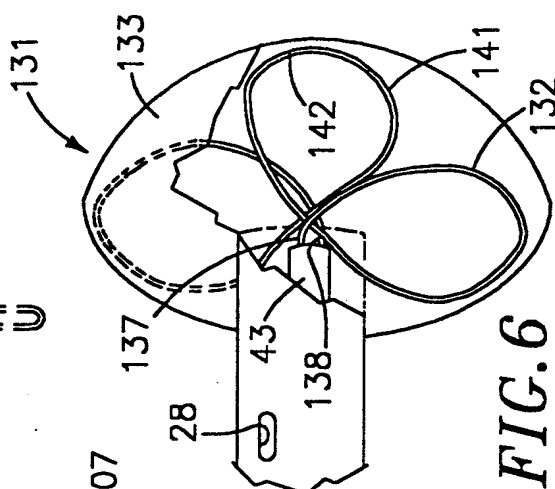
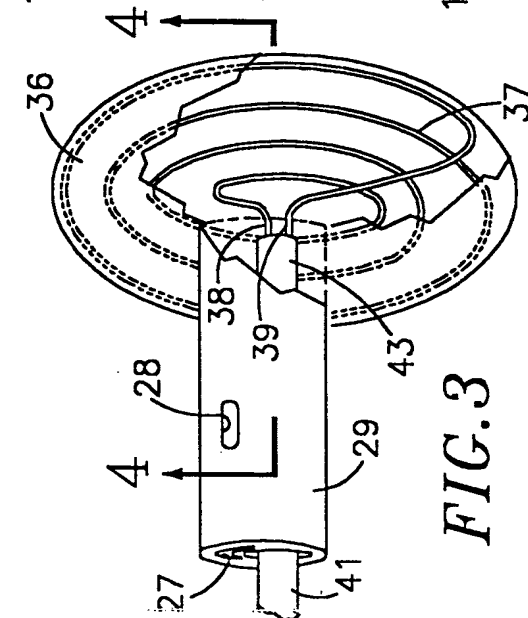
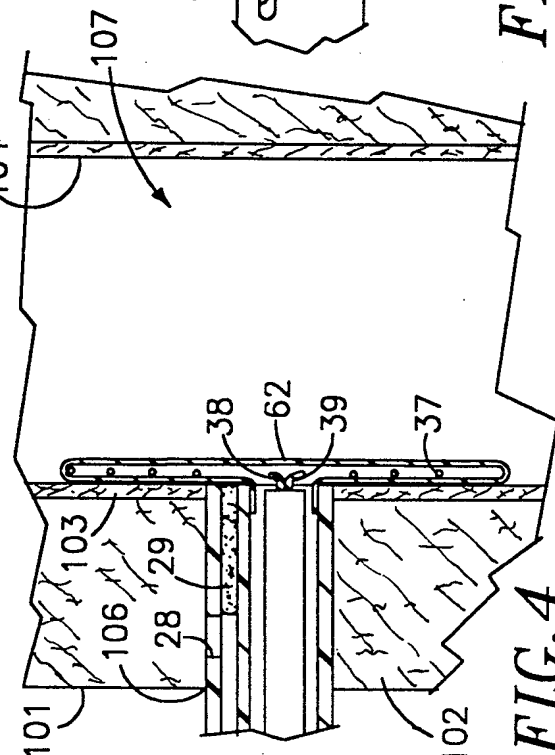
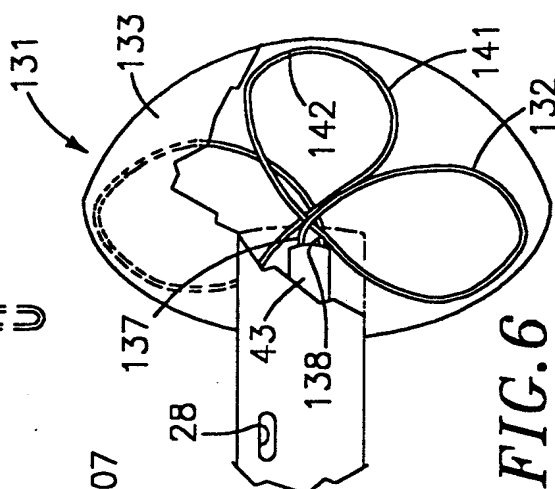
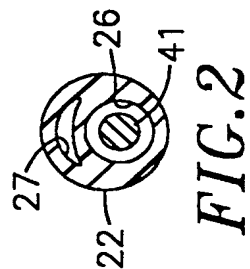
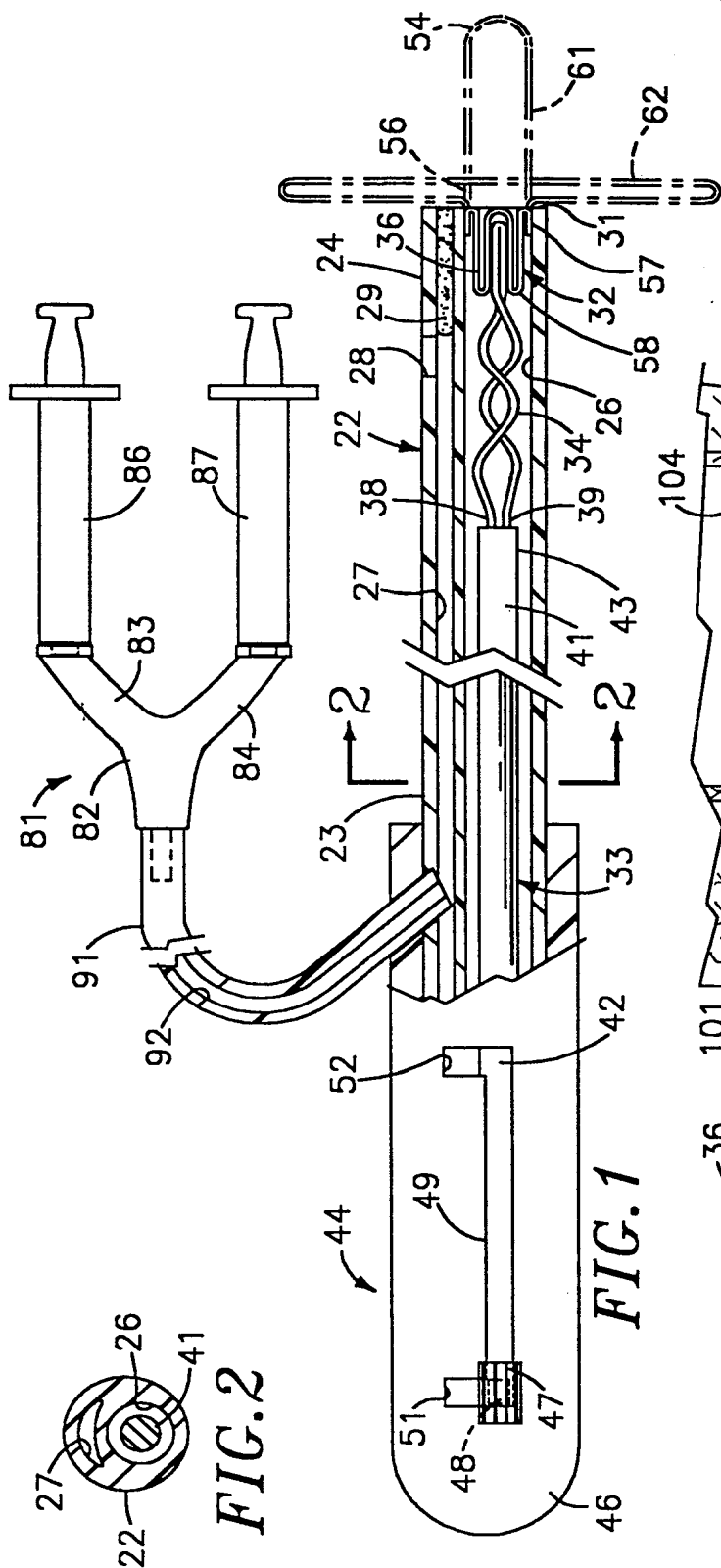
47. A method for percutaneously expanding a device in  
a blood vessel having a wall defining a lumen in the human  
body by use of a device having a elongate tubular body  
25 having proximal and distal extremities and having a  
longitudinal axis, said elongate tubular body having a first  
elongate tubular member having proximal and distal  
extremities and having a longitudinal axis, said first  
elongate tubular member having a lumen extending from the  
30 proximal to the distal extremity, a second elongate tubular  
member having proximal and distal extremities and having a  
longitudinal axis and having an inner wall defining a lumen  
extending from the proximal extremity to the distal  
extremity of the second elongate tubular member, said first  
35 elongate tubular member being nested within the lumen of the  
second elongate tubular member thereby defining a first

5 space between the first elongate tubular member and the  
inner wall of said second elongate tubular member, a third  
elongate tubular member having proximal and distal  
extremities and having a longitudinal axis and having an  
inner wall defining a lumen extending from the proximal to  
10 the distal extremity of said third elongate tubular member,  
said second elongate tubular member being nested within the  
lumen of the third elongate tubular member thereby defining  
a second space between the second elongate tubular member  
and the inner wall of said third elongate tubular member, an  
15 expansile member carried by the distal end of said elongate  
tubular body, a deformable membrane covering the expansile  
member and being carried by the distal end of the first  
elongate tubular member, said membrane being sized so as to  
be capable of overlying and underlying the expansile member  
20 in the expanded and deployment means carried by the proximal  
extremity of the elongate tubular body and adapted to be  
operated by the human hand, the method comprising  
introducing the distal extremity of the first elongate  
tubular member and the expansile member through the wall  
25 into the lumen of the vessel so that the expansile member is  
disposed distally of the wall of the vessel, moving the  
expansile member from a contracted position to an expanded  
position, pulling the first elongate tubular member  
proximally to bring the expansile member into engagement  
30 with the wall of the vessel and waiting for a predetermined  
amount of time, thereafter moving the expansile member from  
the expanded position to a contracted position and removing  
the device from the vessel.

48. A method as in Claim 47 together with the step of  
35 applying a predetermined proximal force of tension to the  
expansile member after bringing the expansile member into

5 engagement with the wall of the lumen of the vessel and  
releasing said tension before moving the expansile member  
from the expanded position to a contracted position.

49. A method as in Claim 47 together with the steps of  
introducing a biological sealant after the expansile member  
10 has been brought into engagement with the wall of the vessel  
to cause the biological sealant to surround the distal  
extremity of the first elongate tubular member and to fill  
the space between the wall of the vessel and the expansile  
member, permitting the biological sealant to cure for a  
15 predetermined amount of time, thereafter moving the  
expansile member from the expanded position to a contracted  
position and removing the expansile member from the  
biological sealant.



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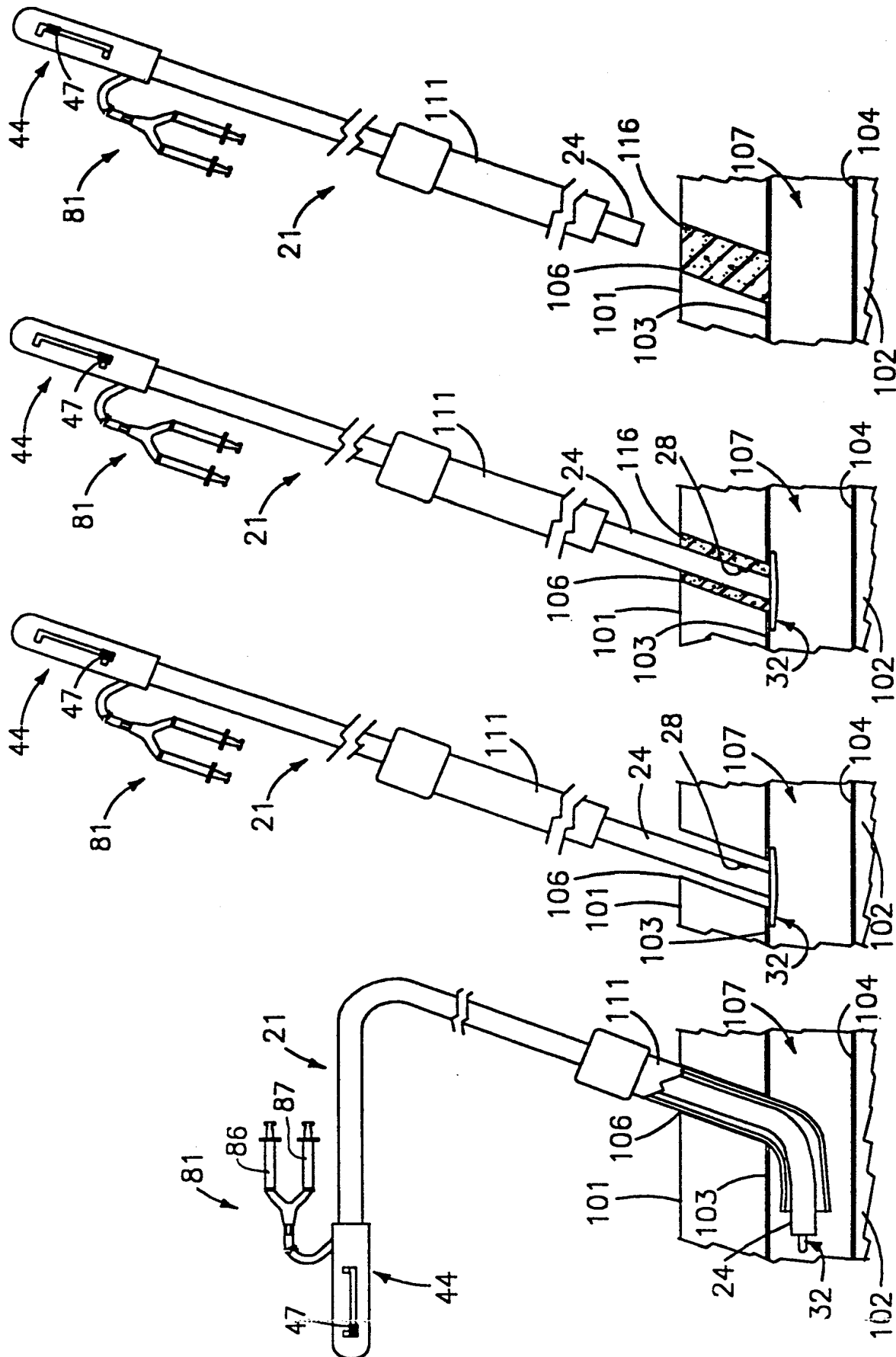


FIG. 5D

FIG. 5C

FIG. 5B

FIG. 5A

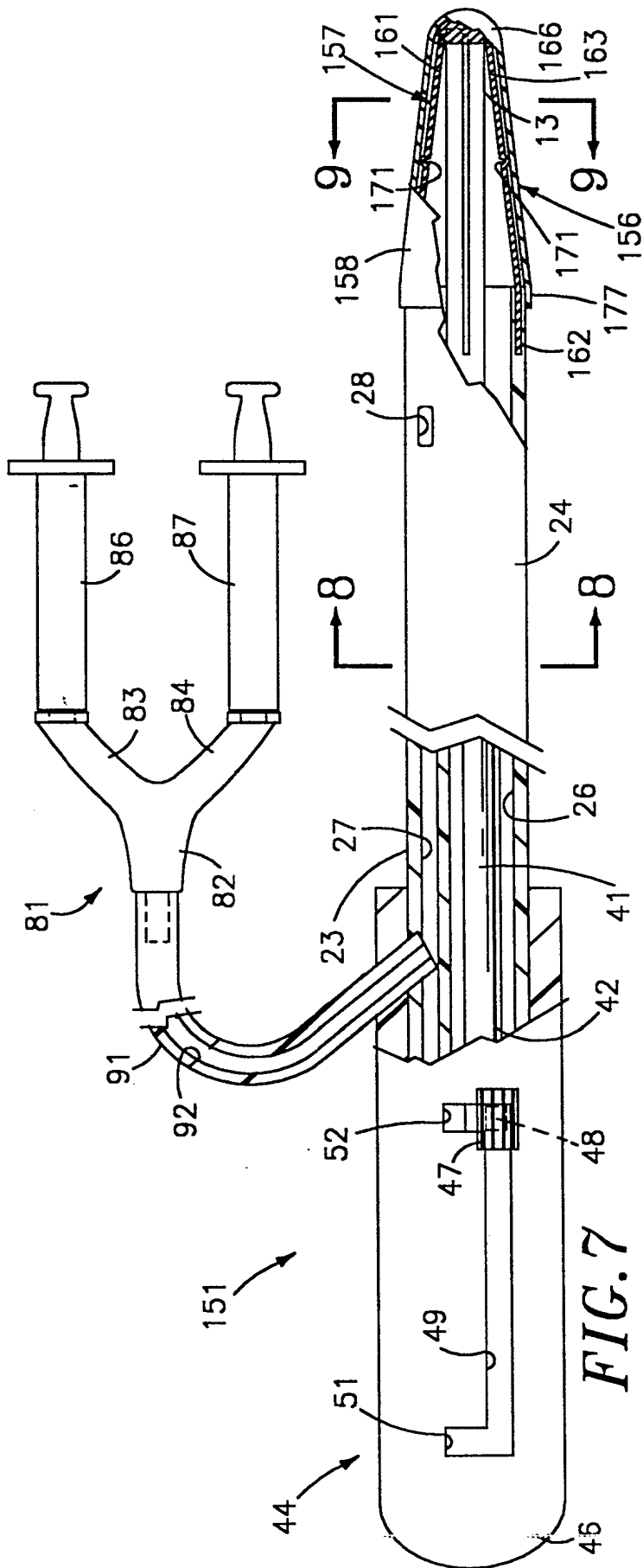


FIG. 7

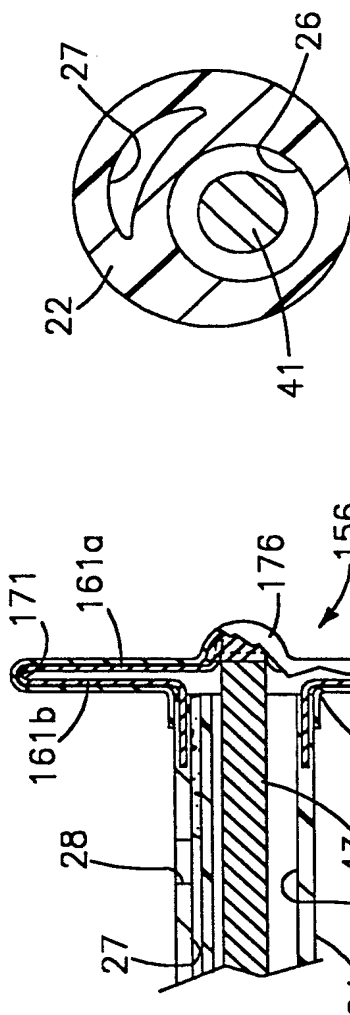


FIG. 8

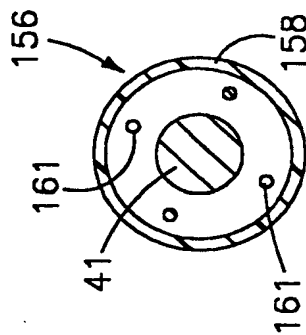


FIG. 9

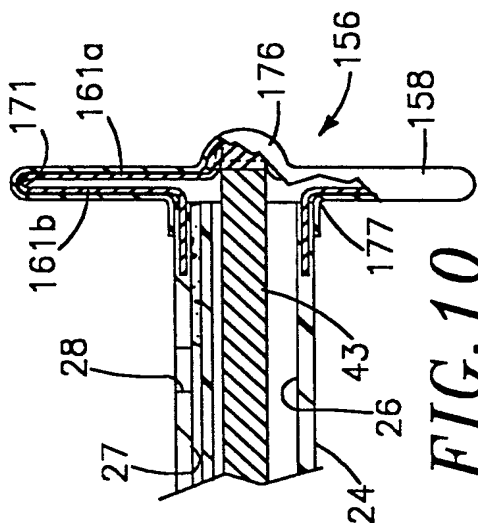
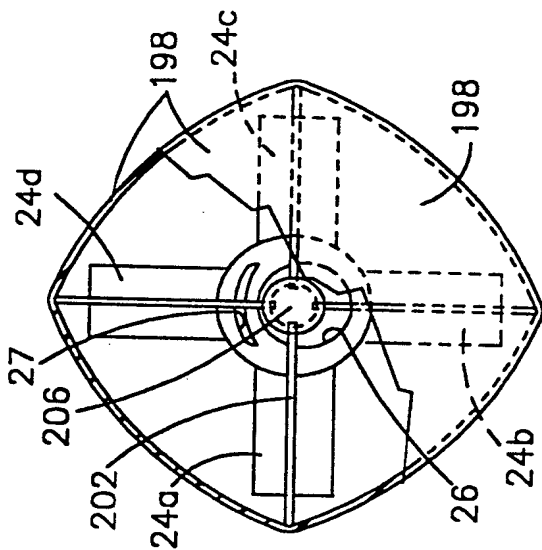
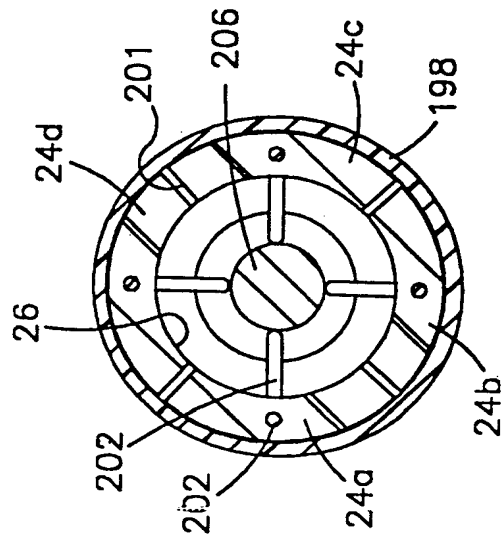
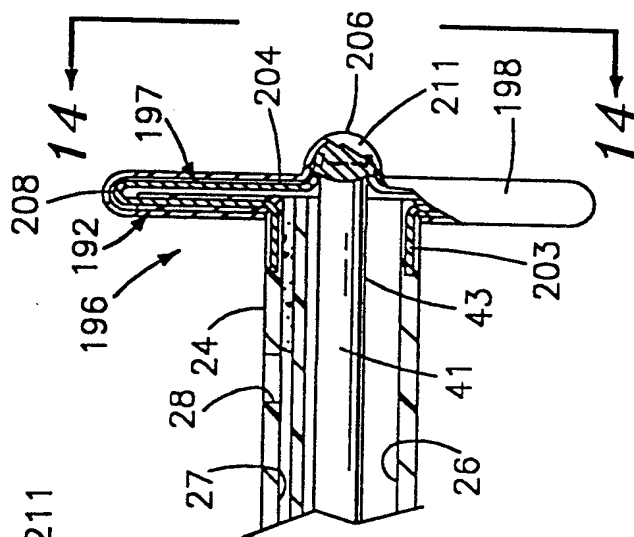
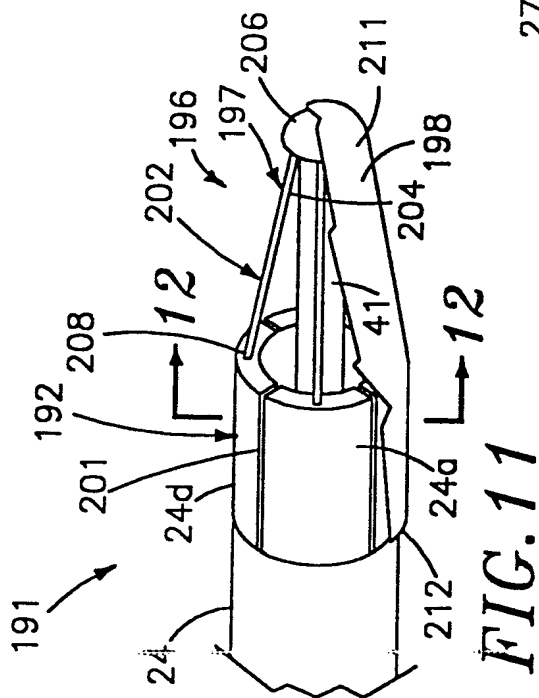
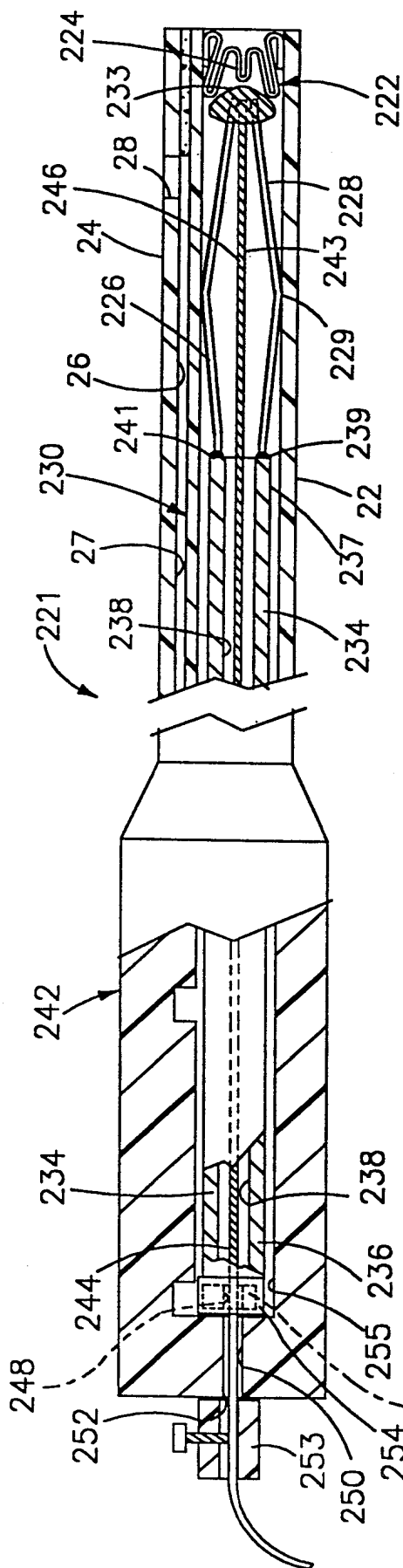


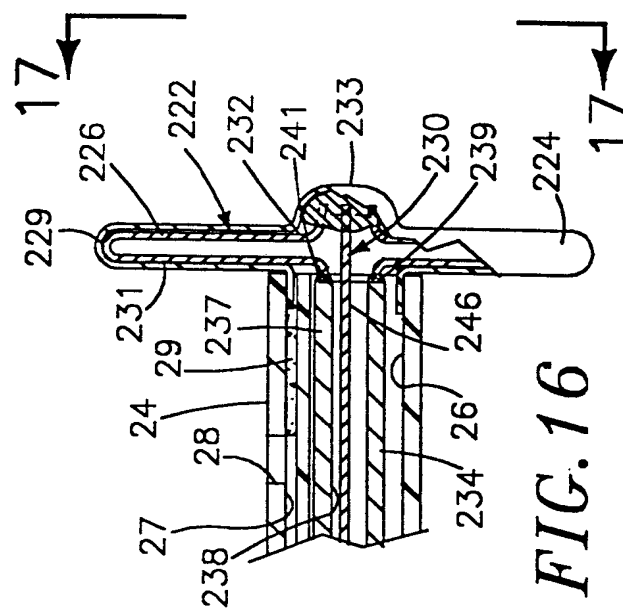
FIG. 10

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**FIG. 15A**



**FIG. 16**

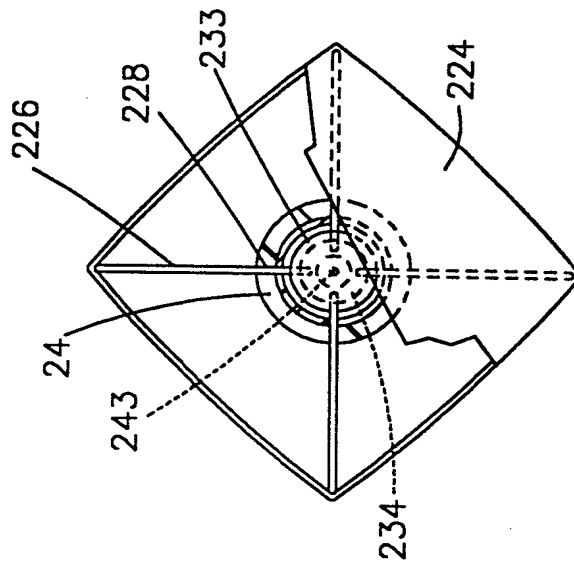


FIG. 17



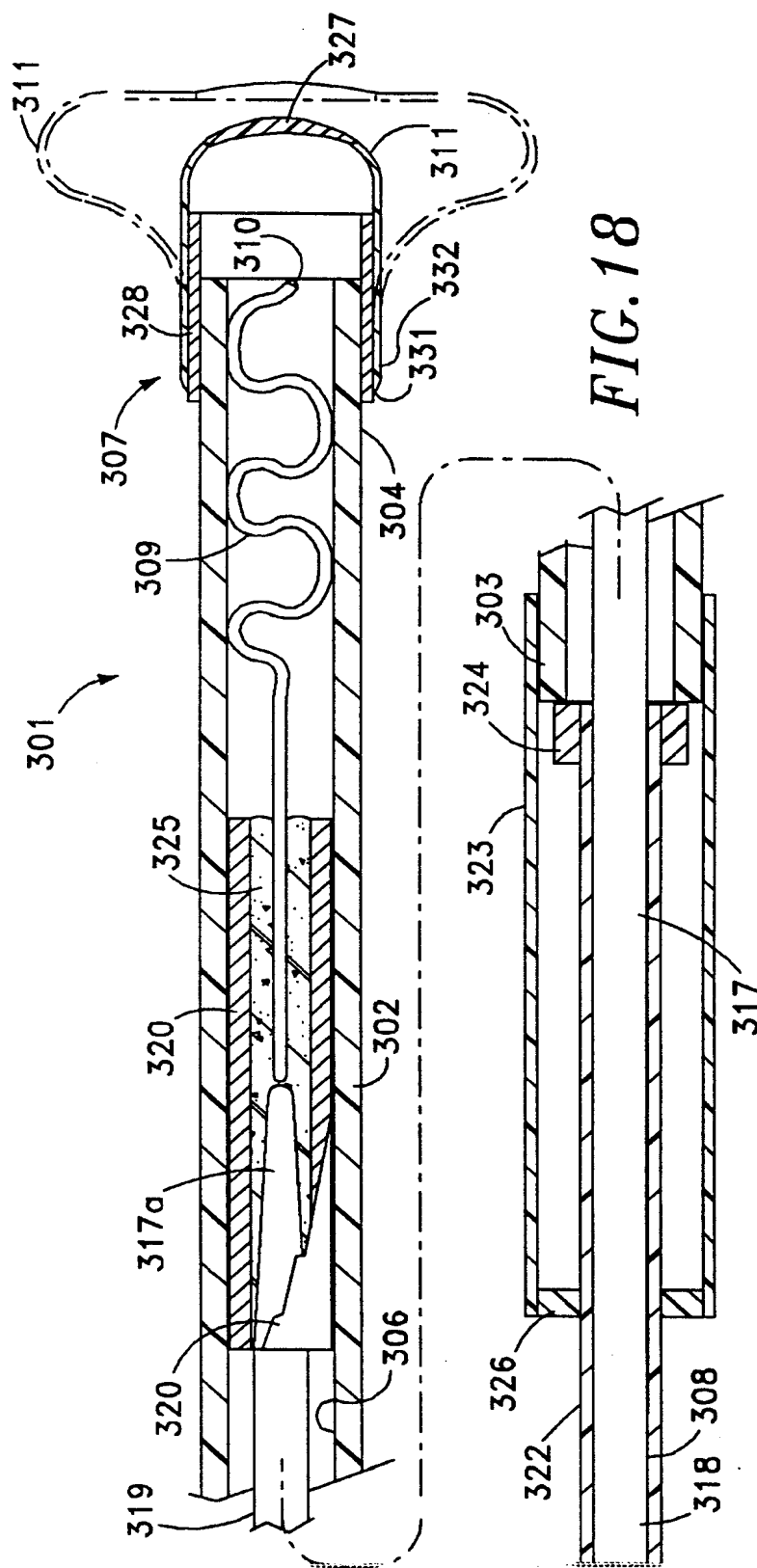


FIG. 18

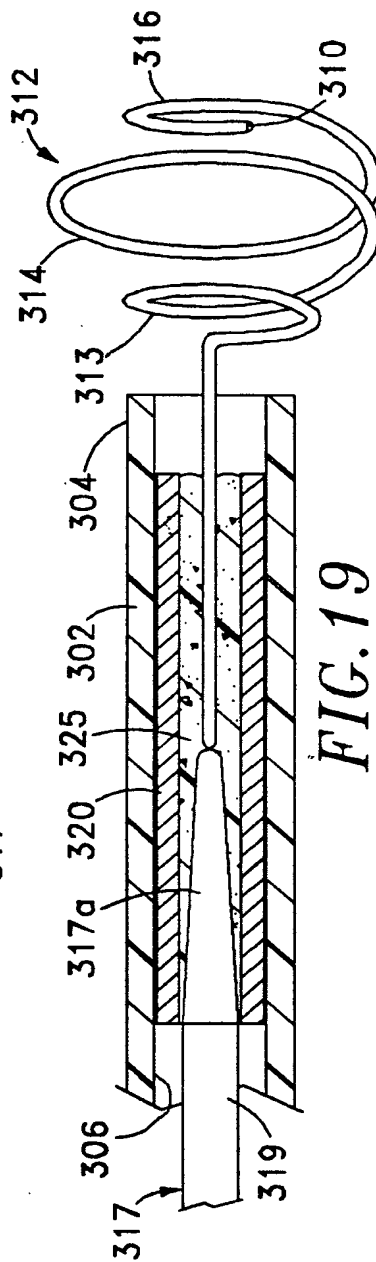


FIG. 19

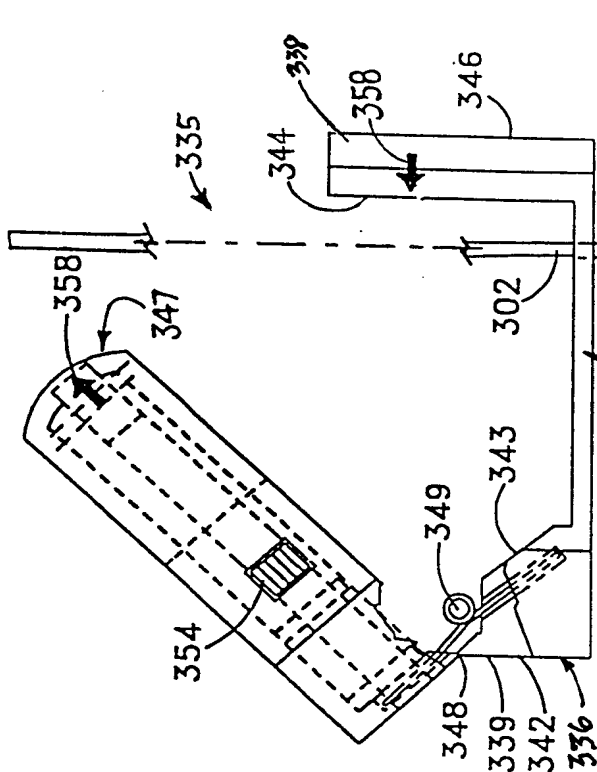


FIG. 22

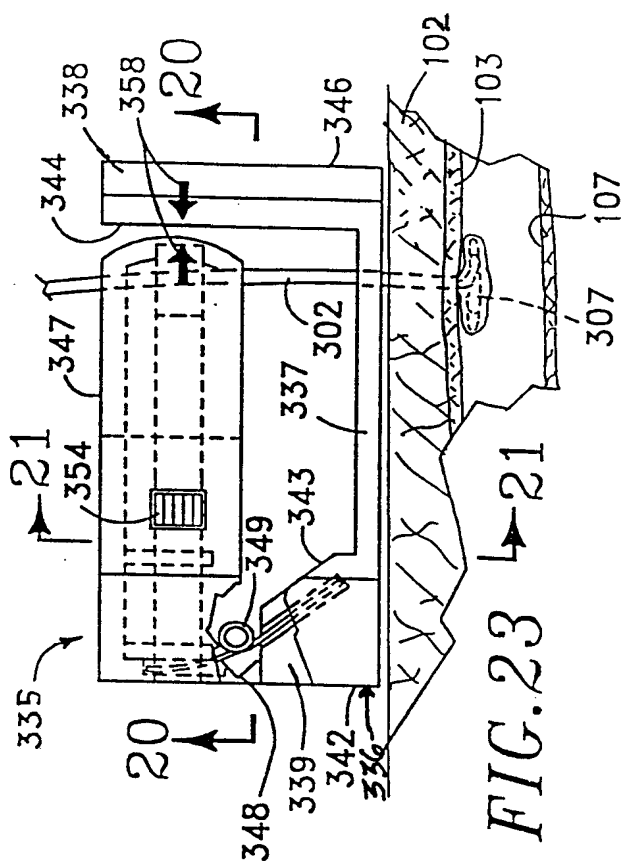


FIG. 23

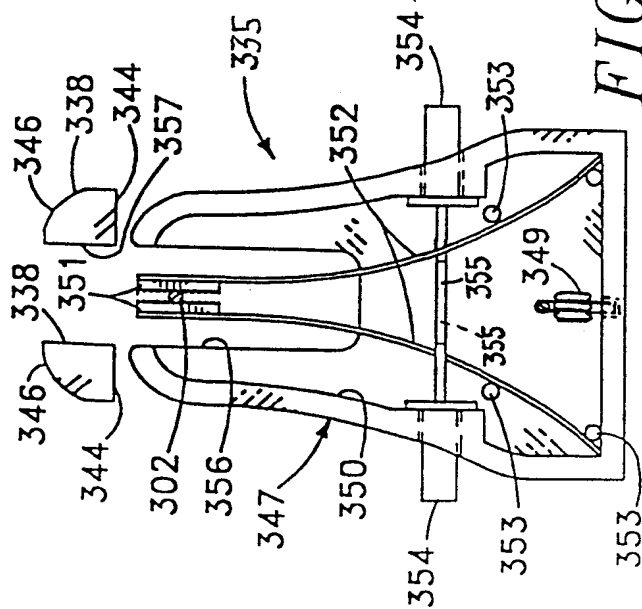


FIG. 20

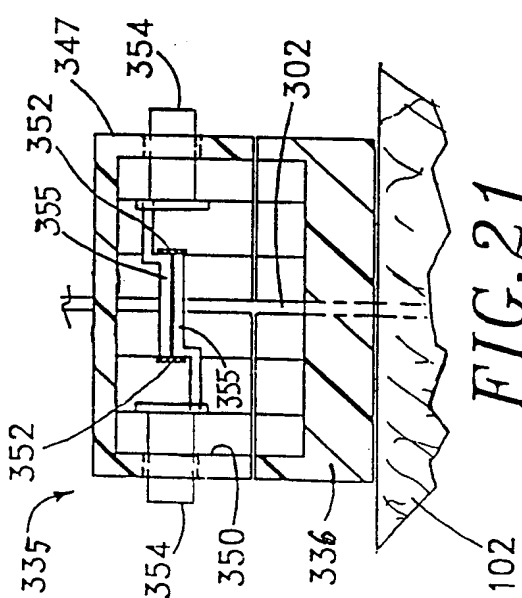
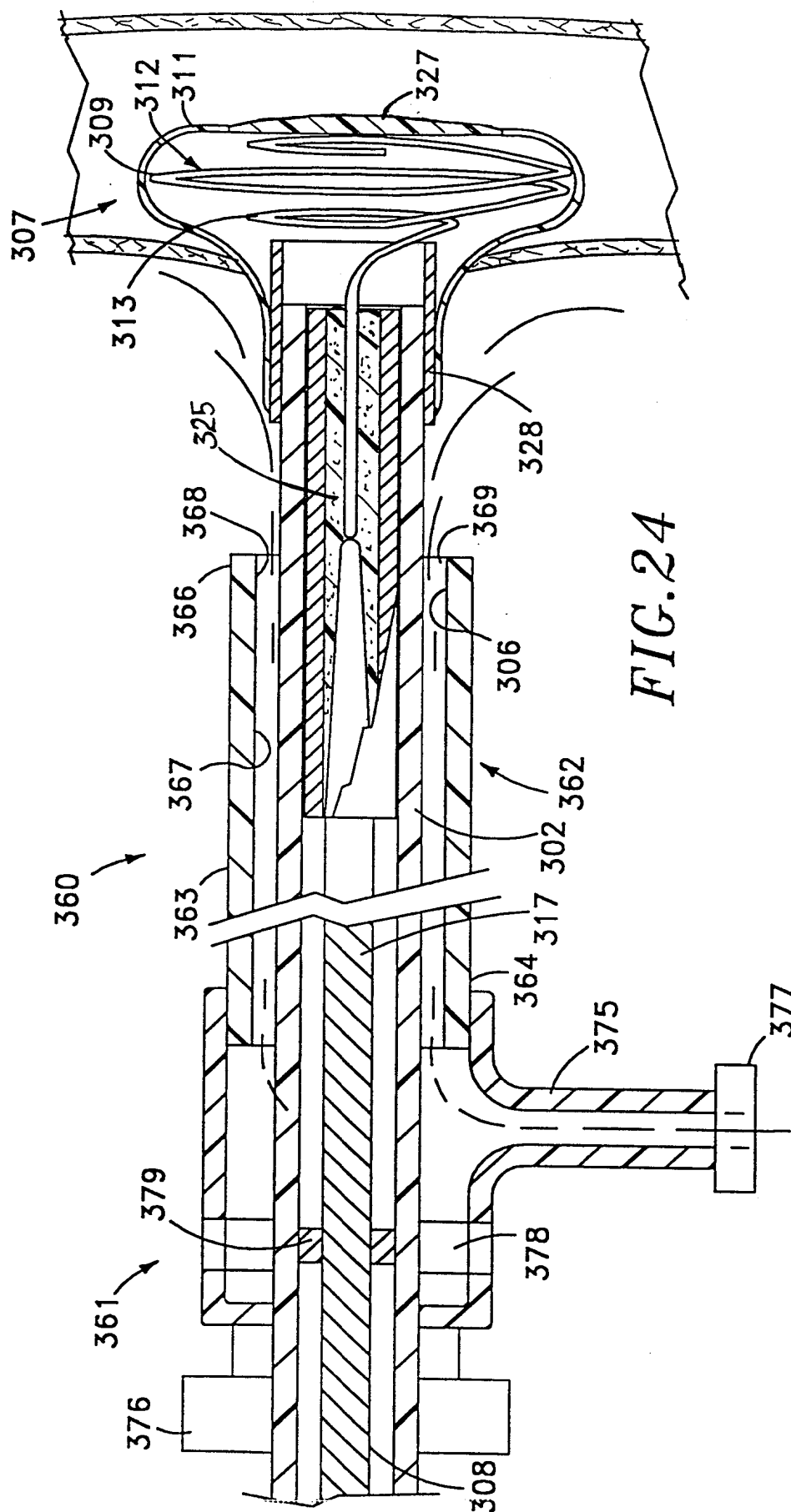


FIG. 21



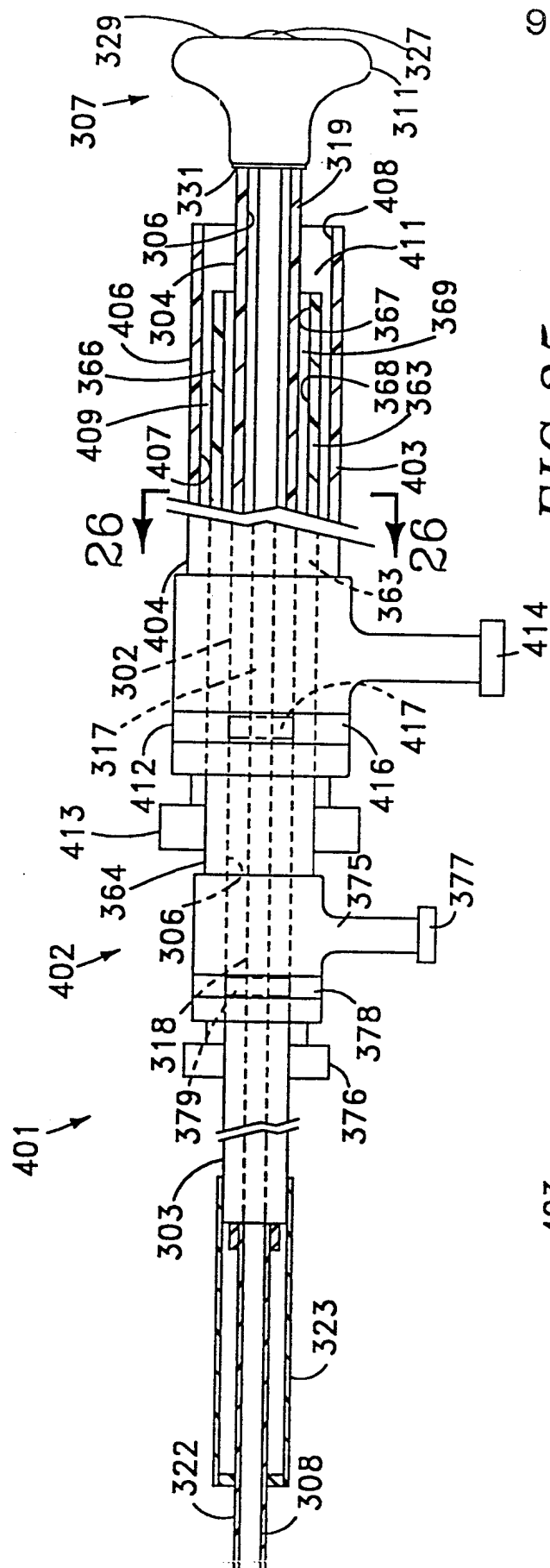


FIG. 25

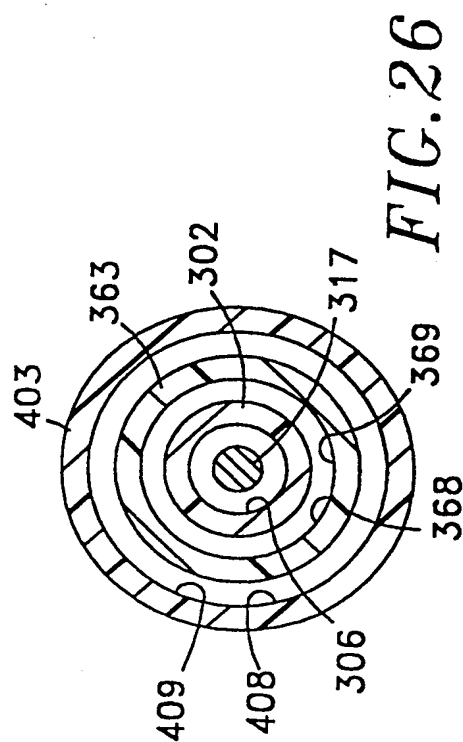
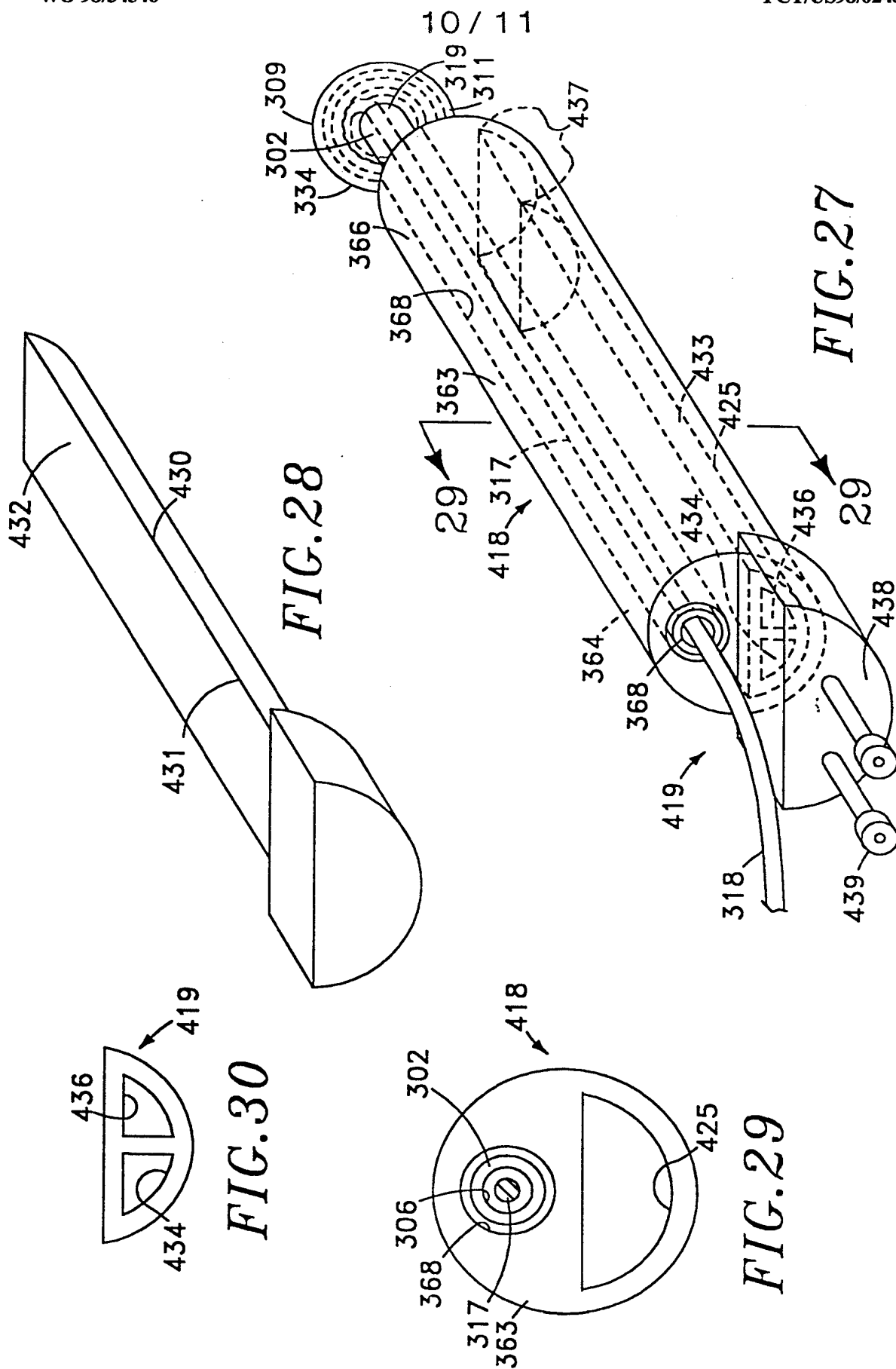
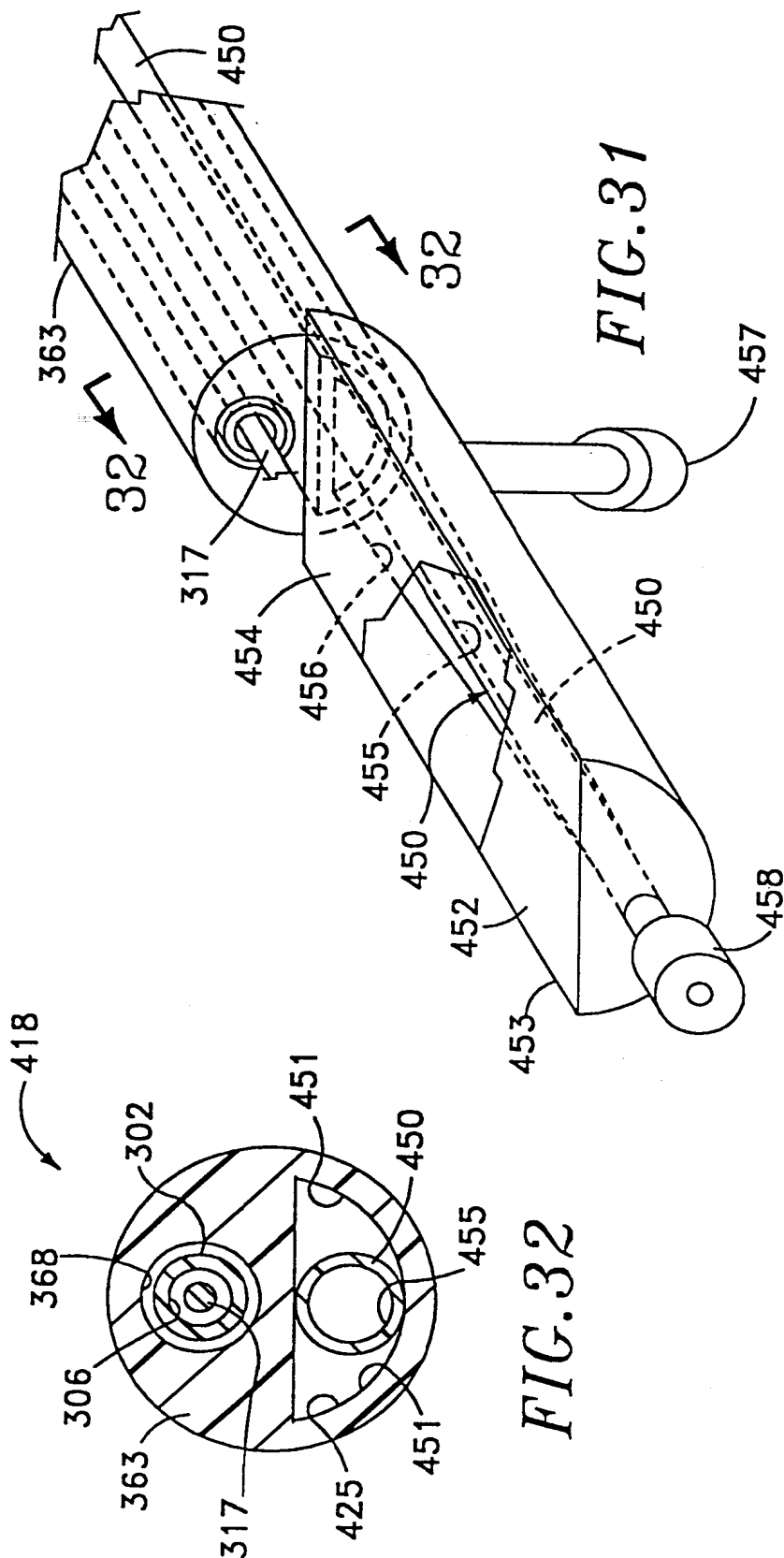


FIG. 26





## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/02483

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/04

US CL :606/139, 144, 213

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96; 606/139, 144, 213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,171,259 A (INOUE) 19 December 1992, col. 1 lines 35-68; col. 2 lines 1-21, and col. 3 lines 1-7.	1-9
Y	US 5,454,833 A (BOUSSIGNAC et al) 03 October 1995, col. 1 lines 44-67, and col. 2 lines 1-45.	9
A	US 5,108,421 A (FOWLER) 28 April 1992, col. 2 lines 33-69, and col. 3 lines 1-3.	10-24
A	US 5,419,765 A (WELDON et al) 30 May 1995, col. 2 lines 10-65.	30-49



Further documents are listed in the continuation of Box C.



See patent family annex.

"	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 JUNE 1998

Date of mailing of the international search report

24 JUN 1998

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